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Conference on Federal - State Implementation of Public Law 90-602

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ORO-69-3	Report of State and Local Radiological Health Programs. Fiscal Year 1968
ORO-69-4	Conference on Federal-State Implementation of Public Law 90-602, March 24-28, 1969, Montgomery, Alabama.
ORO-69-5	Radiation Sources in Secondary Schools. Report of a Limited Survey. 1969

ORO 69-4

Conference on Federal-State Implementation of Public Law 90-602

March 24-28, 1969
Montgomery, Alabama

Cochairmen:

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September 1969

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Consumer Protection and Environmental Health Service
Environmental Control Administration
Bureau of Radiological Health
Rockville, Maryland 20852

FOREWORD

The Bureau of Radiological Health continues to carry out a national program designed to reduce man's exposure to ionizing and non-ionizing radiation.

Within the Bureau, the Office of Regional Operations assists and advises the Bureau Director on regional and State radiological health activities. This office coordinates all radiological health activities for our active Federal-State partnership to achieve and maintain comprehensive radiological health control. The Office of Regional Operations assists in the field implementation of the Radiation Control for Health and Safety Act of 1968, Public Law 90-602. The Office of Regional Operations also guides and directs the State participation in Public Law 90-602.

The Bureau publishes its findings in *Radiological Health Data and Reports*, (a monthly publication), the *Environmental Health Series*, Public Health Service numbered reports, appropriate scientific journals, and division or office technical reports.

The technical reports of the Office of Regional Operations (ORO) allow comprehensive publishing of the results of intramural and contractor projects. The reports are distributed to State and local radiological health personnel, Bureau technical staff, Bureau advisory committee members, university radiation safety officers, libraries and information services, industry, hospitals, laboratories, schools, the press, and other interested individuals. These reports are also included in the collections of the Library of Congress and the Clearinghouse for Federal Scientific and Technical Information.

Your additional comments on these reports or requests for further information are encouraged.

John C Villforth

John C. Villforth
Director
Bureau of Radiological Health

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PREFACE

This publication contains the proceedings of the Conference on Federal-State Implementation of Public Law 90-602, the "Radiation Control for Health and Safety Act of 1968." It was held March 24-28, 1969, in Montgomery, Alabama, cosponsored by the U. S. Public Health Service, Bureau of Radiological Health and the Conference of Radiation Control Program Directors. One hundred sixteen persons representing all but two of the States, local radiation control agencies, and the Federal government met on this historic occasion, the first such meeting of its kind.

The meeting was held in response to the call for a Federal-State partnership in the implementation of Public Law 90-602. The Act, which became law on October 18, 1968, focused on the growing public health problem of exposure to ionizing and non-ionizing radiation. Sections 356 and 357 of the Act emphasize the importance of State involvement in its implementation and the identification of the measures and assistance needed to strengthen State radiation control programs.

The program was divided into general sessions and ten workshop sessions involving all participants.

The general sessions presented reports on the status and meaning of Public Law 90-602 and on technical questions involving ionizing and non-ionizing radiation. A highlight of the general session was the presentation by Chris A. Hansen, Commissioner of the Environmental Control Administration, on the role of States and regional Bureau of Radiological Health offices in control of radiation.

Due to a number of complex topics presented at this meeting, the 116 participants were assigned to ten workshop groups. Each workshop discussed a topic in detail and presented a comprehensive report to the entire group on the last two days of the meeting. Some of the workshop topics dealt directly with various questions concerning the implementation of Public Law 90-602; others covered broader radiation control questions of national and State scope. The report of each workshop is contained in the proceedings.

The objectives of this meeting were to identify areas of Federal-State partnership in the implementation of Public Law 90-602, determine the most effective means to involve the States in this implementation, assess the needs of Federal and State radiation control programs to meet the challenge of Public Law 90-602, and to acquaint State and local authorities with the Act and the future plans of the Bureau of Radiological Health. In addition, discussion was directed to broad problems of radiation control not specified in the Act but closely related, such as control of radioactive materials. All questions were directed to meet the problem of reducing unnecessary exposure of the public to ionizing and non-ionizing radiation.

James W Miller

James W. Miller, D.D.S.
Acting Director
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SUMMARY

A. Radiation Control Problems

The conference identified a number of constraints to State participation in the implementation of Public Law 90-602 and the control of radiation hazards:

1. Lack of adequate funds for State and local agencies to control ionizing and non-ionizing radiation sources,
2. Insufficient manpower and instrumentation in many States to adequately deal with both ionizing and non-ionizing radiation,
3. Growing number of uses and types of radiation sources,
4. Gaps and inconsistencies between various control agencies in regulations and priorities,
5. Lack of sufficient coordination between State and Federal programs,
6. Lack of adequate standards and regulations for non-ionizing radiation sources,
7. Insufficient involvement of State programs in development of standards and model regulations,
8. Undue emphasis on some radiological problems at the expense of radiological problems of greater public health importance.

The workshop groups discussed these constraints and recommended methods and resources necessary to overcome them.

B. Recommendations

The conference workshops emphasized the importance of involving State and local radiological health programs in the implementation of Public Law 90-602 and the need for coordinating State, local, and Federal radiation control activities. The Conference of Radiation Control Program Directors, representing all State and local programs, was identified as the major organization with which Federal agencies should work to achieve coordination and action. The participants unanimously called for an annual meeting sponsored by the Bureau of Radiological Health, of State, local, and Federal radiation control programs to plan and implement solutions to radiation control problems.

Workshop recommendations on specific problems are detailed in the proceedings of this conference. The highlights are summarized below:

Radiation Control Activities

1. The first priority of a radiation control program should continue to be the reduction of unnecessary healing arts X-ray exposure.
2. Radiation control programs should expand their scopes to encompass all forms of radiation other than mechanical vibration as specified in Public Law 90-602.
3. All radioactive materials, whether Atomic Energy Commission "agreement" materials or not, should be regulated in the same manner by State and Federal agencies.
4. Environmental surveillance activities of the Federal Government should be curtailed in favor of source-oriented flexible State-operated environmental monitoring programs, with all collected data made available by the Bureau of Radiological Health for general distribution.
5. The Department of Health, Education, and Welfare, should assume regulatory responsibility in Federal installations for radiation sources currently not subject to regulation by the U.S. Atomic Energy Commission.

Implementation of Public Law 90-602

1. The Department of Health, Education, and Welfare, should enter into agreements with qualified State radiation control programs for the conduct of inspections and compliance activities associated with the administration of Public Law 90-602.
2. An ad hoc committee of State radiation control program directors should be established to advise the Department of Health, Education, and Welfare on the effective implementation of Public Law 90-602.
3. Continuing committees should be established with representation from Federal, State, and local radiation control programs to further study and implement the specific recommendations of the various workshops.
4. The Department of Health, Education, and Welfare, the Atomic Energy Commission and other interested Federal agencies should continue to support and sponsor the Conference of Radiation Control Program Directors in an annual workshop.

Program Support

1. The Department of Health, Education, and Welfare, should expand its support of Federal, State, and local radiation control activities in the form of increased operating funds and grants, State assignees, and instrumentation.

2. The Department of Health, Education, and Welfare, and the Atomic Energy Commission should continue to expand their support of technical training activities in radiation control including short-term and university-based educational programs.

Standards, Legislation and Regulations

1. Federal, State and local agencies should participate in the formulation of regulations, standards and model legislation.

2. State radiation control programs should use model legislation and regulations to assure uniformity and compatibility among the various control programs.

3. The Conference of Radiation Control Program Directors should request the National Council on Radiation Protection and Measurements (NCRP) to consider the problems of exposure to sources of non-ionizing radiation.

CONFERENCE ON FEDERAL-STATE IMPLEMENTATION OF PUBLIC LAW 90-602

INTRODUCTORY REMARKS

The Conference on Federal-State Implementation of Public Law 90-602 convened in the Civic Room, Jefferson Davis Hotel, Montgomery, Alabama, Monday, March 24, 1969, and was called to order at 1:30 p.m. by Dr. James W. Miller, Chairman.

DR. MILLER: If you will all be seated, we will get under way with the first working conference with all the State radiation control program directors. I am really pleased to see many familiar faces. I am Jim Miller, your Chairman for this meeting, and on my right is Tom Gerusky, my Cochairman.

I would like to get the meeting started off right, and I will ask Dr. Ira Myers, State Health Officer for the great State of Alabama, to give us a proper welcome.

WELCOME

Ira L. Myers, M.D.[1]
and
John E. Regnier, Ph.D.[2]

DR. MYERS: Dr. Miller, ladies, and gentlemen, it is a pleasure for us to have you in Alabama. We are Number One in the alphabet and would be Number One in everything else if we tried hard enough, because we really work at it. We even work on poverty. I think that in many of the programs that are national in scope, we either find ourselves at the top or at the bottom.

We are grateful for the assistance that we have had from the Atomic Energy Commission and the Public Health Service in providing us a good program in radiological health. We are fortunate in having the fine facility of the Public Health Service here, in our Regional Laboratory. We have been able to use this facility for a variety of purposes. We started off with treating "mad dogs," and then we treated polio. We did some investigation of virus diseases and now we are in this exotic world of ionizing and non-ionizing radiation, and the implementation of the law, the subject of this conference. We just don't hesitate a bit in the world to call on the Public Health Service when we get in a jam.

I am sure that you in the other 49 States and the District of Columbia that are represented here are anxious to begin the conference, and we are delighted that you are here. The subject matter which you will be taking up is of real importance to us and to you. We are sort of innocent bystanders in this particular program because our host is outstanding in public health service. We hope that you will pick up some good points on how we can do a better job from the State level to coordinate a program that has Federal, State, and local responsibilities. We will do our best after this conference to implement the things that we have learned here in theory and the cooperation we have talked about by putting them into practice.

It is real nice to see so many people here, so many friends from all over this fine country. We hope this will be not the end but the beginning of a very fine friendship with each of you.

DR. MILLER: Thank you, Dr. Myers. I can assure you it is a pleasure for all of us to be here.

It is my pleasure to introduce your host for this meeting, Dr. John Regnier, Director, Southeastern Radiological Health Laboratory.

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[1] State Health Officer, Alabama Department of Public Health.

[2] Director, Southeastern Radiological Health Laboratory, Montgomery, Alabama.

DR. REGNIER: Ladies and gentlemen, I would certainly like to second Dr. Myers' comments in welcoming you to Alabama.

I would like to welcome you to visit our laboratory out on the edge of town, and we are happy to provide transportation for you. In fact, we have some tours set up. I would encourage you and welcome you to come and visit us at any time during the week.

Again, let me just wish you a very pleasant, productive meeting. I know this is a first in having almost 50 States represented in one meeting. It is the first for all of us, so I am looking forward to a very productive week.

DR. MILLER: Thank you, John.

Our next speaker will be Dr. Raymond Moore, Acting Director, Bureau of Radiological Health, who will tell us of the changing role of the Bureau; its missions, goals, objectives, and priorities.

THE CHANGING ROLE OF THE BUREAU OF RADIOLOGICAL HEALTH ITS MISSION, GOALS, OBJECTIVES AND PRIORITIES

Raymond T. Moore, M.D.[1]

A few days ago I found a little quotation that I liked very much. It ran something like this, "We would worry less about what others think of us, if we realized how little they do."

Now, folks, that doesn't hold in this radiation protection business we are in now. We are being scrutinized, we are being looked at, we are being thought about, we are being discussed. Getting together the bulk of the public health experts in this country on radiation, and that is what you are, to study and work together, and attempt to solve some common problems, has created additional interest.

If you will look at the program before I get into my prepared statement, you will note that we in our Bureau have really brought to you the problems as we see them.

Last October, the passage of Public Law 90-602 placed upon all of us a tremendous responsibility. In the workshop sessions, the topics of compatibility, radiation protection, criteria and/or indices, performance standards for radiation users, and others will be examined. This is a tremendous opportunity for us in the Bureau of Radiological Health and the States to get together and chart a course for the future.

During the ten years that I have been in radiological health, and this makes me somewhat of a neophyte among many of you, I have seen a very great change in emphasis. It is a dynamic sort of thing. We worry about different things at different times, and are man enough to realize that we must adjust to the times; we must grow, we must maintain some cognizance or some surveillance over the multitude of problems. I am impressed by the fact that as long as radiation is in the title of our Bureau, or in the title of your State agencies, you can never duck a question in radiation. You can try, others may duck it, but it is going to come right back to us just by nature of having it in our agency title.

Let me describe for you some of the things that we have been doing. Let me reacquaint you a little bit with the history of what is now the Bureau of Radiological Health. As you know, we have been a Division, we have been a Center, and we are now a Bureau. The Division of Radiological Health was formed in 1958 under the broad authority given to the Surgeon General for performance of research activities related to the control and prevention of physical and mental diseases and impairment of man. That Act also authorized the Service to cooperate with, and to aid, State and local authorities in the enforcement of their health regulations, and to collect and disseminate health information.

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[1] Associate Commissioner, Environmental Control Administration, CPEHS, Public Health Service. Formerly, Acting Director, Bureau of Radiological Health, Public Health Service.

One of my earlier mentors in the Division of Radiological Health, Public Health Service, told me that the most important function he performed was carrying news and information from one place to another. In many respects, that is what we were empowered to do.

During the early years, our primary concern fell into four broad areas. The first of these was the concern over radioactive fallout from atmospheric nuclear weapons tests. Indeed, you might say that is where we got our start. I would be remiss if I didn't recall to your attention the interest of Mr. James G. Terrill, Jr., over the years, in nurturing and developing this program. We were concerned then with the impact on the health of the general public, and with the means of measuring this impact, and the design and development of countermeasures which could be effective in alleviating potential hazards, if any were required.

Second, we had a concern over the use of radium and other sources of radiation not controlled by the Atomic Energy Commission. The use and integrity of the radium sources and appropriate leak-testing procedures were areas which received our attention. From the beginning, we recognized that diagnostic radiology in the healing arts represented probably the greatest potential man-made exposure to the general population.

Third, early attention focused on the inspection and correction of the physical defects in X-ray equipment. Development of the dental surpak and other survey techniques assisted the State and local agencies having the prime legal responsibility in this area.

Fourth, was the awareness that manpower requirements in the radiological health area were of such magnitude that a definite need to assist State and local agencies in fulfilling their program obligations was not only desirable, but essential. Over the years, we in our Bureau used approximately one-fourth of the resources that were made available to us by Congress under the broad heading of "training." Approximately one-fourth of this is a deep commitment to train manpower. If I asked for a show of hands, I imagine the majority of you have taken one or more BRH training courses. We felt that we should not only do short-course training for one or two weeks, but we had to manufacture new types of manpower. We had to take our own people and put them through universities for advanced degrees. It is not possible for me to overemphasize the importance we have put into this training effort over the years. Along about 1962, Congress appropriated some categorical forms of grant monies for utilization by States. Through this mechanism and others, you were able to get a radiological health program of some category, at least identified by name, I believe, in every State. Your name on the wall or bulletin board is very important, because if your name is not on the bulletin board, you are not there, I am finding out.

Throughout all of these activities, we have tried to provide good technical advice and consultation. We had a small effort in developing model legislation and model regulations. We had an effort in standard survey and inspection procedures which could be utilized by States. Of the things that we have done, this is one that, maybe at the time, we didn't realize how important it was, but I certainly do now.

In short-course training, one or two weeks' duration, we estimated that some 2,200 people will take one or more of the short courses. This fiscal year, we estimate that some 400 people will be trained through the university-grant mechanism, wherein we support the radiological health program in 41 States. Some 400 masters and technician level degrees, including some doctors of philosophy, are to be granted this year. This is a tremendous impact, but this is not a very large percentage of the need when we now start surveying and thinking of the responsibilities that we have before us.

Through the years, program emphasis has been modified to meet changing needs and priorities. As the hazards of atmospheric testing and its associated fallout have diminished, we have changed the emphasis of the surveillance programs. They now take into account the manpower requirements we have touched upon, the siting of nuclear facilities, and the potential pollution of the environment, including the thermal implications. The peaceful uses of atomic energy will probably require an entirely different type of surveillance from the type that we have had in the past. There may be problems with krypton and zinc to mention only two. Really, the thing that I am most confident of is that right now we probably do not know which one of these may be the most important five years from now. So we must have a responsive surveillance program.

We touched a bit on the use of radioisotopes in medicine. Our interest in these has expanded tremendously. The use of radioisotopes in nuclear medicine is expanding. We do not yet know the final magnitude of this application. We know that the use of iodine-131 has probably made up over half of the application to date. There are many other applications possible. We still will need almost the same formula: trained people, better isotopes, or more usable isotopes, and better instruments.

We need to strengthen the protection from unnecessary exposure of the population to X-rays. Much has been done, but much needs to be done. During the 1964 X-ray Exposure Study it was made clear that as improvements were made in the physical facilities, additional attention must be directed to the users of these machines, and to assure that the operators are properly qualified and most importantly, motivated in the best techniques possible. We must likewise develop performance standards and criteria for new X-ray machines, and devise effective means for controlling the sale and resale of used machines which may be defective.

The passage last year of the Radiation Control for Health and Safety Act of 1968 is probably the most significant piece of Federal radiation legislation since the passage of the Atomic Energy Act in 1954. The import of this bill requires us to take a new look at our priorities and goals. We have expanded our interests and concerns beyond the ionizing area into non-ionizing emissions such as microwaves and lasers. As the potential hazards associated with these various emissions are determined, we must establish performance standards and control mechanisms to minimize the dangers. And don't forget, this must be done in such a way that the beneficial uses of these devices and our technology are not constrained. We have a balancing act, of the benefit versus risk. We certainly believe in it.

It is of interest to me, and I am sure will be equally interesting to you, to note that the implementation of this law has been given a priority second only to the quality of the environment of the urban ghettos. That spells a great deal.

As our highly technical society continues to advance, we have a wealth of new electronic products, and varying uses of existing products continue to come to the surface. At the latest count, there were approximately 5,400 manufacturers in the United States reputed to produce an estimated 30,000 different types of electronic products. We must sort out these products on some sort of a rational basis. Those with hazardous radiation must be identified and performance standards set for them. Those without hazardous radiation must be allowed to find their place in our market place.

To do all of this, we must have a close working relationship with all of the State radiological health programs, as well as with many of the electronic product industries, their associations, and a number of other Federal agencies. You and I know that the States have the principal responsibility for the health and safety of their population. Much of our program effort will be geared towards assisting the States to carry out these responsibilities, for we do have something valuable to offer. In a way, this is not a new orientation, but rather a reemphasis of a policy established some ten years ago when we proceeded to encourage and assist in the development of State programs.

As you are all aware, in the field of radiological health, there are broad, interstate areas of responsibility requiring program efforts at the national level. It is our hope and intent that the two efforts, State and Federal, can be successfully operated as a partnership, and that this will result in a coordinated and uniform radiation protection program.

Let me emphasize that the term "partnership" implies equality. It implies responsibility. It is our intent to utilize the partnership concept in the planning and decision-making level, wherever possible, as well as in the operational aspects of the total program. This places an increased burden upon State programs to develop the best possible program. In other words, our concept of partnership implies responsibilities as well as benefits.

I am sure that the presentations you will hear the rest of the afternoon and tomorrow, and at the workshop sessions, will bring you viewpoints on specific items of concern to you.

Let me emphasize that I think it is a must that we develop this week some useful guidance in these areas. We have high hopes for the successful outcome of this meeting. We have not spared much, if any, of our staff in the planning of this meeting. Let's not fail to take advantage of this tremendous opportunity that we have this week.

DR. MILLER: Thank you, Dr. Moore. We appreciate your taking time from your busy schedule to be with us and to give us those words in person.

In preparing the program, we thought it would be appropriate to have a discussion on Federal-State cooperation in the control of radiation in the past, and in the present. We wanted someone who would really tell it like it is, so we asked Mr. E. Frank Wilson, Director, Division of Radiological Health, Arkansas State Board of Health, to give his views on this subject.

FEDERAL-STATE COOPERATION IN THE CONTROL OF RADIATION PAST AND PRESENT

E. Frank Wilson[1]

It is a real pleasure to be here with such a knowledgeable array of radiation protection specialists and to have the opportunity to look at the past, the present, and look towards the future.

As I look back over the years that radiological health has been in existence, one wonders what really took place. What kind of coordination and cooperation have we had between the Federal and State governments? What has been accomplished to protect the public from harmful radiation?

The first time that I can recall that we did anything in our State, and probably in most States, was the concern of health authorities about the hazards of radioactive fallout. As you may recall in the early 1950's many rumors were prevalent concerning the testing of atomic devices at the National Test Site near Camp Mercury, Nevada. The major concern dealt with the contamination of our milk and food supplies.

As the testing programs progressed, the United States Public Health Service, Division of Radiological Health, was given the assignment to monitor radioactive fallout in the offsite areas. In order to do this, the United States Public Health Service asked for assistance from the States in the form of people to assist in the offsite monitoring operations. These people were assigned principally to the communities surrounding the test site but also to the on-site group for work in the laboratory.

The United States Public Health Service, State, and local government employees worked together as a team to accomplish a well-defined objective: the protection of the citizens in the area surrounding the National Test Site from dangerous levels of radioactive fallout. This fine team effort continued throughout the test periods until the test ban was signed and in effect. This is the finest example of Federal-State relationship I have personally observed and I hope that the tone of this meeting can establish the same pattern for the new program we are entering.

Public Law 90-602 sets up the legal mechanism whereby a joint working system can be established between Federal and State government. This meeting has been called by the United States Public Health Service, Bureau of Radiological Health, for the purpose of setting out the mechanism whereby it is possible to again establish a team system working for protection of our citizens from radiation hazards. This is an opportunity for all of us attending this meeting to sit down together and set out the best system for attacking the problems of control of this environmental hazard.

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[1] Director, Division of Radiological Health, Arkansas Department of Health.

In order to better understand the problems of organization and application we are faced with here, let's digress to other areas of Federal-State programs and what have been the results.

It is highly likely that most of us in our past, as public servants, have had experiences with other governmental agencies. These experiences have varied from poor to excellent, but generally they have been, at best, mediocre. Most State people complain that cooperation has been a one-way street. On the other hand, Federal agencies feel that State government does not take its share of the responsibility for programs. While neither of these views is probably correct, it does give us an opportunity to show how it should be done. This, I feel, is one of the best reasons we are meeting this week.

In the formative years of our present program, the necessary ingredient to get our program going was leadership. The United States Public Health Service gave our region an abundance of this in the form of Doctors McMartin, Moore, and McTaggart. Certainly, leadership is a must, and that must is in this meeting in the form of program directors from most of the States and from the Federal agencies involved in radiation control.

In this initial phase of the program, the United States Public Health Service representatives were working in the field with the State radiation health people, and it was hard to tell us apart. This was a learning process for both groups. Field surveys were being made; information collected, coded, and sent to Rockville for card punching and data evaluation. With luck, we were able to get our data back in two years. Now, we do these and other operations ourselves. This is as it should be, that is, each State should be self-supporting as far as these services are concerned.

Economics is the great program leveler. Programs and program objectives must rely on the amount of money made available to program directors. If you have 500 licensees and 5,000 X-ray units to be surveyed and no money to hire personnel, it's quite obvious that you are not too likely to make much progress towards inspecting these facilities. Originally, our program, like most, was funded on a categorical-type grant based on population and geography, but need was not considered. We were required to match the funds allotted to us on a one-for-one basis. Under the Comprehensive Health Plan now used, we are given a priority. Under this system, we are not required to match money, but are required to go into competition with other programs for a share of it. In our State, this was a reduction in funds for all programs in the health department because the top 15 percent went to mental health. Our budget was reduced by approximately this amount.

In order that we in radiation health divisions can better obtain money to use in the electronic product work, I would suggest that a contractual system be established whereby an agreement is made on what work is to be done and a price established for it. We have a similar arrangement with the Department of Defense for calibration and maintenance of the Civil Defense radiation monitoring equipment. They buy services from us on a long-time contract that is reviewed annually and modified as needed. This puts these monies within the grasp of the program director.

Except for some rare instances, we in the States rarely undertake research. If we do, it is applied research of field testing. We do not have the money, time, equipment, or personnel for this type of program. This applies to ionizing radiation as well as non-ionizing radiation. This has been the case in the past and should be the case in the future. Our role in the States is to do the field work, surveys, inspections, data collection, field test equipment as developed by others. In the past, the States have not been consulted on the programming of this type of activity. Therefore, I propose that an advisory committee be established to coordinate the various activities in which the Environmental Control Administration and States will have common interest. Public Law 90-602 has provision for this type of activity.

It is necessary to stay in a constant state of training in our field. If we do not, the new people being recruited will not be expert enough to properly handle their job, or may become disenchanted and seek another career. Those who have been in the field a number of years also need to be kept abreast of the new developments, instrumentations, etc. We need both short- and long-term training. We have this now in the form of short, one- to four-week courses and United States Public Health Service sponsored graduate level scholarships. I urge the United States Public Health Service to continue training at the current level.

In addition to the semiformal and formal training, there should also be some type of on-the-job training. This type of training can be beneficial to both Federal and State people. The United States Public Health Service needs new employees trained in field operations at the State level and their research people need to test their equipment to determine its feasibility. On the other hand, State people need on-the-job training in survey techniques, laboratory procedures, and environmental monitoring.

On most property owned or controlled by a Federal agency, little or no attempt has been made to control ionizing radiation. This has been, and probably still is, the prerogative of the local Federal administrations. They do not know, and we do not know, what types, kinds, energy, quantity, or quality of radiation that persons on these lands are exposed to daily. There are no regulations, rules, and control except for Atomic Energy Commission controlled material. These people who work in these installations reside in our States where their fellow workers in private or State installations are regulated and controlled as to their exposure to ionizing radiation is concerned. This situation should be remedied as soon as possible. Federal employees should be required to abide by the same or similar safety standards as the rest of the country.

There are a variety of problems that we in the States constantly encounter. It should be recognized that each State is different from its neighbors. Quite often, you in Federal agencies fail to recognize this or possibly choose to ignore it. When you make arbitrary decisions you quite often fail to recognize the problems you create in the States. The fact that each State is different is important. Our legislatures appropriate our monies, give us our enabling legislation, and require answers to them for the conduct of our programs. We must, as program directors, go before our State legislative bodies to request new monies, explain the conduct of programs, and explain how the last appropriation was spent. Therefore, it is necessary that we inform them, as well as all citizens, how new programs will benefit them or protect them.

Therefore, I urge you, in undertaking this new law that we spend our time and our energies where it will do the most good, not where it is most interesting. At present, we are required to accept what manufacturers of X-ray equipment for the healing arts produce. Medical-dental X-ray exposure is still the largest area of unnecessary exposure, and our first emphasis should be in this area.

DR. MILLER: Thank you, Frank.

Our next speaker, Dr. William A. Mills, is Chief of the Division of Biological Effects, Bureau of Radiological Health, and is here to talk about a very timely subject, the biological effects from non-ionizing radiation.

BIOEFFECTS OF NON-IONIZING ELECTRONIC PRODUCT RADIATION

W. A. Mills, Ph.D.[1]

While I will concentrate my remarks on non-ionizing radiation, I may have to talk a little about ionizing radiation. I don't want you to get the impression that we are experts in non-ionizing radiation. This is as new to us as it is to you, but I think it is an exciting field, and one in which we can really make a contribution. I am impressed with this conference, because if I read the attendance correctly, among you, you represent something like 200 million people who are interested in the radiation aspects of public health. Like Ed Wilson, we too are faced with a shortage of funds, and because of this shortage, we have to rely pretty much on our expertise in ionizing radiation.

I will make the point now, that we are not in any way reducing our efforts in ionizing radiation. I think Ed put his finger on it when he said that we still have a long way to go in medical and dental X-rays.

Interest in the biological effects of non-ionizing radiation has received a new prospective in public health with the introduction of such electronic products as microwave ovens into private homes. However, this interest is not solely in microwaves, but under the enacted Public Law 90-602, includes the entire electromagnetic spectrum, intense magnetic fields, and the sound spectrum.

Today, I will discuss briefly our findings from examination of the literature in some of these areas of non-ionizing radiation. Some of my remarks are from staff papers being prepared by the Division of Biological Effects. These papers are to be published within the next several months. Other remarks have been taken from reports published by the Bureau of Radiological Health on the bioeffects of microwaves and lasers. For a more complete review, indicating references, the staff papers should be consulted.

Ultraviolet

The ultraviolet region of the electromagnetic spectrum is intermediate in wavelength and frequency between the X-ray and visible regions. The limits of the ultraviolet portion are not clear-cut and may be considered to be electromagnetic radiation of wave length between 40 and 4,000 angstroms (A), or of frequency between 7.5×10^{16} and 7.5×10^{14} hertz (Hz), respectively. From a biological standpoint, the dividing line between ultraviolet and X-ray spectra may be considered to be at about 1,000 A (3×10^{15} Hz), where atoms and molecules can be ionized.

In the intact animal, the incident ultraviolet radiation does not penetrate through the skin. Below 2,900 A absorption in humans is entirely in the epidermis. Between 2,900 and 3,200 A, less than 10 per cent reaches the dermis. Over 50 per cent of wavelengths above 4,000 A reach the dermis. It is, therefore, obvious that internal organs are not liable to ultraviolet-induced damage.

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[1] Director, Division of Biological Effects, Bureau of Radiological Health, Public Health Service.

The ultraviolet from any given source depends on the source and on the absorbing material around the source. For example, a quartz envelope in place of the phosphor-coated glass of an ordinary fluorescent lamp would convert that lamp into a powerful germicidal lamp emitting chiefly 2537 A radiation.

Any shielding between the ultraviolet source and the intact animal either reduces or eliminates the ultraviolet. With few exceptions, media which transmit visible light may be suspected of transmitting ultraviolet.

Whole-body exposure to ultraviolet radiation is possible, with present day mores, only among those persons practicing nudism. Common articles of clothing are effectively opaque to ultraviolet.

The critical organs for ultraviolet radiation are the skin and the eye. The skin is the main absorber of ultraviolet and reacts by erythema, tanning, and pigment darkening. The erythema, a reddening of the skin as a result of dilation and engorgement of minute blood vessels in the dermis, may be accompanied by slight swelling of the exposed region. Severe exposures result in blistering and desquamation. Pre-erythemal histological changes in exposed skin are not evident. About the time erythema is detected, intracellular edema and migration of leukocytes into the irradiated region begin.

Ultraviolet exposure of the eye may cause painful corneal burn and blindness. To estimate the radiation required to produce such effects, one investigator has measured the power density emanating from a source under conditions which led to one painful case of corneal injury. Based on the accident, he estimated that 10 microwatts/cm^2 from a germicidal lamp (principal ultraviolet is at 2537 A) for 20 minutes could produce the corneal injury.

Ultraviolet radiation incident on the eye is absorbed successively by the cornea, the aqueous humor, the lens, and the vitreous humor. In the intact eye, ultraviolet radiation does not reach the retina. It is obvious, however, that removal of portions of the eyes, such as cornea in cataract operations, decreases the ultraviolet absorbing media.

Visible Light

Visible light covers the narrowest of the various electromagnetic wavelength bands, approximately 4,000 to 8,000 A, and is, as the name implies, the only one perceived by the human eye. The penetrating ability of visible light is slight except for transparent materials such as water, glass, and the lens and humors of the eye.

Because of its narrow depth of penetration, visible light in general does not manifest itself as a potential hazard. However, there are situations in which it can become hazardous. Probably the one of greatest danger is that of high intensity light which may cause (1) transient loss of visual function (flash blindness), or (2) irreversible thermal injury of the retina.

Flash blindness is a relatively new problem to man occurring only since man has developed sources of light brighter than the sun. It results from the bleaching of the visual pigments. Flash blinding can be prevented with proper filtering of light when the occurrence is expected. The second of these effects on the eye, irreversible thermal injury, has been known for years. For example, lookouts for airplanes have on occasion suffered retinal lesions which appear to be caused by heat generated at the sun's image on the retina.

In summary, it can be stated that, excluding lasers and masers and special focusing devices, the visible light range presents little biological hazard _per se_ except to the eye. With regard to the eye there appear to be three predominant factors controlling the potential of the hazard: (1) intensity, (2) pupil dilation (i.e., area of exposure), and (3) length of exposure. If these factors can be controlled to keep the absorbed energy below the threshold of thermal burning, reported to be between 40-50 calories/cm^2 per minute, no eye injury would be expected.

Infrared

Infrared radiations have longer wavelengths (8,000 to 10^6 A) and are the radiations we "feel" when holding a hand up to the fire or a hot object. From the standpoint of biological effects, the quantum energy in the infrared spectrum is sufficient to induce an increase in molecular and intramolecular action which is recognized as heat. Infrared radiation of 12,000 A has been shown to penetrate tissue to a depth of about 3 millimeters, but penetration decreased rapidly with an increase in wavelength because of moisture on the skin. Due to its shallow penetration, the sensation of heat is quickly detected and can therefore give adequate warning that extreme conditions exist.

The fundamental action of infrared is heating. If the heating is sufficient, burns of the skin, cataracts in lens of the eye or retinal burns will occur. The iris in the eye appears to absorb the radiation and increase the heating effect of the lens which is particularly sensitive because of its poor heat-dissipating mechanism. In addition, infrared sources can increase the thermal load on man so that his sweating mechanism cannot compensate to lose enough heat. High body temperatures may develop, with resultant heat stroke or heat exhaustion. Heat cramps may also occur because of excess loss of salt.

Two cases of radiant burns resulting from operating room lamps have been reported. Commonly there is a complaint that heat is too intense before burning would occur. But if there is a loss of skin sensation, the pain will not be felt. In the two cases mentioned above, the patients were under anesthesia, had the blood supply to the "operative area" clamped off to prevent bleeding, and had the light focused on the same area for a considerable length of time. The results were third degree burns in the "operative area." Radiant energy of about 2 calories/cm^2 per minute is near the burn threshold level and likely to cause burns if modifying factors occur, such as poor blood circulation, dark skin colors, or environmental factors which limit heat dissipation.

The last point to be mentioned is that of retinal burns and cataract formation. While the components of light which produce damage are the same for visible and infrared radiation, there are rather marked differences between the two. Burns resulting from visible light usually require a longer latent period since the light causes the pupil to constrict; hence a longer time is required to absorb sufficient energy (heat) to cause a burn. However, infrared radiation, not being visible, can be delivered through the widely dilated pupil. This wide-open pupil will admit roughly 50 times the energy per unit time that a small pupil will. This can also happen in combination with visible light where the peak energy is delivered in such a quick burst that the pupil or eyelid does not have time to react. Since infrared radiation does not cause constriction of the pupil, it is important to realize that glasses with high absorptive powers in the visible region may be very dangerous if they also have a high transmission in the infrared region; retinal lesions have occurred when the sun has been observed through such lenses.

Lasers

Lasers emit highly directional, spatially confined, beams of intense monochromatic radiation. Of the possible biological effects of laser radiation studied to date, the eye appears to be the most sensitive organ to injury. The lens of the eye focuses the incident visible laser radiation upon the retina resulting in an energy density at the retina of several orders of magnitude greater than the incident level at the cornea. For this reason, corneal intensities of visible laser radiation that could produce retinal damage are many orders of magnitude less than the incident intensities required to produce skin damage.

The action of laser radiation on biological tissues may be divided into two broad areas: (1) those attributed to heat; (2) those not attributed to heat (nonlinear effects). These nonlinear effects include mechanical effects such as target recoil, pressure effect from thermal expansion, shock wave production, free radical formation,and harmonic generation of other wave lengths in crystalline tissue components.

Laser-induced thermal lesions have been produced in various tissues in several animal species and in man. A theory that has been advanced to explain thermal injury includes: (1) thermal alteration of protein; (2) other possible alterations in metabolic processes; and (3) non-protein induced alterations in physical characteristics of cells.

The absorption of high-intensity energy in the visible and near-visible portions of the electromagnetic spectrum by the eye has long been known to cause ocular damage. For radiation in the visible, near-ultraviolet, and near-infrared regions of the electromagnetic spectrum, the retina is considered the critical part of the eye, whereas in the ultraviolet and infrared regions, the portions of the eye anterior to the retina may be of greater concern. For wave lengths in the near-ultraviolet, visible, and near-infrared regions, the amount of energy required to produce retinal injury is many orders of magnitude less than that required to produce skin damage.

The effectiveness of laser radiation in producing retinal lesions is influenced by several factors: (1) pupil size; (2) spectral transmission through the ocular media; (3) spectral absorption in pigments of the retina and choroid; and (4) retinal spot size.

The threshold value for retinal damage may be defined as the energy density required to produce, within a short interval of time (approximately five minutes) after exposure, a clinically visible retinal lesion. These values should not be taken as the absolute minimum for retinal damage since injury has been demonstrated at lower levels of irradiance by more refined techniques. It has been demonstrated that impairment of enzyme activity can occur at levels of irradiance 10 to 15 percent below those required to produce visible lesions. Also retinal lesions may not become clinically visible immediately after exposure at low levels of irradiance.

Because of the lack of information on the human eye, threshold values are based upon data obtained from experimental animals, mostly rabbits. Extrapolation to the human eye must be made with caution. Research on retinal burns and clinical experience have shown that the rabbit retina provides a useful model for estimating a safe level of human exposure. The energy values necessary to produce threshold lesions are reported to be significantly lower in the rabbit than in the human.

Exposure of the skin to laser radiation is an obvious hazard; however, the biological significance is much less than ocular exposure. There is a high probability that persons who work with laser generating equipment receive repeated exposures to their hands. Studies have been conducted on the skin of animals and to a very limited extent on man using a variety of energy levels and wave lengths. Summarizing the results, a certain energy density was required before there was any noticeable effect, either macroscopic or microscopic. The actual energy density required to produce a minimal skin lesion was dependent upon such factors as the degree of pigmentation, thickness of the keratinized surface, presence of hair, and its color.

Very little is known about the potential cumulative effects produced by repeated subthreshold exposures either to the eye or skin. Current data in this area are not sufficient to provide information concerning the possibility of cumulative effects from repeated exposures. There appears to be some conflict over the significance of repeated subthreshold exposures in the production of damage.

Microwaves

Microwaves are electromagnetic radiations, intermediate in frequency and wavelength between conventional radio waves and far infrared waves. The approximate frequency and wave length characteristics of this type of radiation are 30 to 300,000 megahertz (MHz) and 1000 to 0.1 centimeters, respectively. The exact differentiation as to frequency and wavelength is a matter of definition and common usage.

Existing radar systems utilize frequencies ranging from approximately 100 through 100,000 MHz. Included also in the microwave range are frequencies used in television signal relay, long distance telephony, microwave ovens, and electrotherapy. Frequencies studied with respect to biological hazards have been primarily between approximately 100 and 30,000 MHz. Possible hazards at frequencies less than 100 MHz have been investigated much less.

Considerable discussion has been generated over whether the biological effects of microwaves are caused by an increase in the average kinetic energy of molecules comprising a tissue exposed to microwaves (i.e. due to "thermal" effects) thereby effectively producing a heat injury to the tissues involved; or whether significant effects can be produced in exposed tissue where heating does not appear to be a matter of paramount importance (i.e. "athermal" effects). For the present, these questions have not been resolved, since (1) there still appears to exist a semantic indecision about what to define as "thermal" and "athermal" or "nonthermal"; and (2) most importantly, there appears to be considerable divergence of opinion on what constitutes "a significant effect" of microwaves.

There are marked differences reported in observations by U.S. and Soviet workers in individuals exposed to microwaves. At flux densities of microwaves regarded to be clinically insignificant by many U.S. workers, Soviet scientists have observed a number of varied and frequently serious changes in populations of exposed microwave workers. Both functional and behavioral changes have been reported by the Russians. Because many of the Russian studies have been either poorly or incompletely controlled, for example, with suitable groups of workers as comparison groups, criticism has been leveled at these reports. Nonetheless, a number of highly regarded scientists have urged that efforts on the part of U.S. investigators be instituted to attempt to affirm or deny the claims of Soviet workers.

The levels of flux density reported to produce biological effects in studies reported by the Russians have been as much as one or two orders of magnitude lower than the widely quoted microwave exposure guide of 10 milliwatts/cm^2 in current use in the U.S. Based on Russian observations of microwave workers (including poorly-defined control groups for some of the studies) a clinical syndrome characterized by "asthenia" and changes in autonomic nervous functions has been described. These asthenic reactions have been rather diffuse in nature and irregularly noted. The vagueness of the asthenic symptom complex and its indefiniteness in any but a small fraction of microwave worker groups has probably contributed to the skepticism with which many U.S. scientists have viewed the Russian studies.

The asthenic syndrome defined by the Soviet scientists includes headaches, increased fatigability, memory difficulties, increased irritability, difficulty in sleeping, reduced sexual potency, chest pain, tremor of the hands, and other signs and symptoms, the majority of which are largely subjective. Objective signs reported by the Russians for microwave workers have included changes in the electrical conductivity of the heart, enlargement of the thyroid glands, increased uptake of radioactive iodine by the thyroid gland, increased blood histamine levels, increases in alpha and beta globulins with a concomitant decrease in the albumin/globulin ratio. There have also been reported opacities of the lens of the eye. Other less well-defined findings have included hair loss and brittleness of hair.

Studies of red and white blood cells have been reported by Russian investigators, for individuals whose exposure ranged from very low levels of microwaves (up to a few tenths of a milliwatt) to several milliwatts per square centimeter. There is great variability in the reported blood indices, but in general moderate leukocytosis and reticulocytosis have been noted in exposed microwave workers.

Interestingly, in spite of the great Russian concern and interest in the effects of microwaves on the central nervous system, no reports of clinical neurological evaluation coupled with evaluations of electroencephalographic tracings have been published. Some animal studies have been reported.

In the United States, investigations of exposed microwave workers similar in scope and nature to those of the Russians have been exceedingly few. Two early studies of radar laboratory personnel include a study of microwave workers (about 335 workers) in an aircraft plant and another study of radar workers (about 800 workers) expressly designed to detect microwave effects on the lens of the eye. No other large group studies in the United States have been reported. Instead, the primary U.S. effort has focused on experimental animal studies at microwave frequencies and flux densities which, for the most part, have contributed to knowledge of the thermal effects of microwaves in that most of the studies employed flux densities exceeding 10 milliwatts/cm^2.

The single U.S. study of microwave workers in an aircraft plant failed to reveal any clinical findings directly attributable to microwave exposure with the exception of possible changes in the differential blood counts.

The investigators noted that about 25 percent of the radar workers were aware of heating effects (most often noted with X-band radar). Buzzing vibrations, pulsations, and tickling about the head and ears were noted (with S-band radar). Also, the investigators stated that several radar workers complained of sparking between dental fillings. In this evaluation no unusual or significant differences were recorded between the exposed and the control groups. The authors concluded that the working conditions and exposures did not result in any harmful effects which could be attributed to microwave radiations.

It should be pointed out that this study of aircraft workers suffered from some shortcomings of many of the Russian studies. For example, the control group of workers was poorly defined by the investigators reporting the study. It was not a matched group. Nothing is stated about sex matching although presumably all subjects were males. Apparently the control group was, in general, a sicker group of individuals than the microwave worker group.

In the other large American study, nearly 800 microwave workers have undergone eye examinations in an effort to define the incidence of lenticular injury. In addition, a control group of over 500 non-microwave workers has also been examined. This study was conducted by a clinical ophthalmologist and included slit-lamp examinations of the eye lens. Initial indications were that no differences existed in the incidence of eye pathology in the two groups of workers examined. More recently, however, incipient and overt cataracts have been observed in the microwave-exposed population.

In the above study, 91 cases of microwave lens damage were discovered; 36 of these cases were classified clinically as cataracts (10 mature and 26 immature). The other 55 cases currently exhibit minimal changes, e.g., roughening, thickening, and early opacification of the posterior capsule of the lens. According to the investigator, the threshold flux density seems to be 100 milliwatts/cm^2, although total energy and rate of delivery are unknown. The details of this study are lacking, and it is not clear whether recent observations included a comparable control group of subjects in whom no pathology was found.

The available data on microwave effects based on human experience is quite limited and unsatisfactory. The number of individuals studied to date has been small, the evaluations at times have been cursory or biased, and at no time (other than in the studies on the eye) has there been a long-term evaluation of microwave workers going beyond three or four years. Isolated reports of spectacular effects of microwave radiation including death, hypogonadism, cataract formation, or a possible relationship to mongolism, indicate that these problems exist primarily in an occupational sphere. However, in the light of well-documented (but limited) studies, involving both humans and animals, in which reproducible physiological and behavioral changes have been induced by reported low microwave exposures, the potential of microwaves for causing added burdens of functional, psychosomatic, or behavioral problems in the public sphere should be evaluated as soon as possible.

I should mention that within our Division we have initiated some programs in the area of microwaves. These are:

1. Dr. Russel Carpenter[2], in a "bench-type" consulting arrangement, will be continuing his studies on cataract production in rabbits following microwave exposure. Dr. Carpenter has demonstrated that there is a cumulative effect of subthreshold exposures. This research will be performed at the Northeastern Radiological Health Laboratory.

2. Dr. Maitland Baldwin[3], a neurosurgeon at the National Institutes of Health, has for several years been studying, in primates, changes in electro-encephalograms following radar exposure. These studies are currently being continued in our Rockville laboratory.

3. Dr. Moris Shore[4] and Dr. William Leach[5] are currently conducting some biological experiments using a home-type microwave oven as a radiation source. Dr. Shore is producing some LD_{50} information on rats and hamsters, as well as studying possible changes in protein synthesis. Dr. Leach is doing some chromosomal studies following exposure _in vivo_ and _in vitro_.

4. The Bureau of Radiological Health in cooperation with the Medical College of Virginia is planning a "Symposium on the Biological Effects and Health Implications of Microwave Radiation." This symposium is scheduled for mid-September of this year and will be held in Richmond, Virginia.

Radio and Low Frequency

An area of investigation which is related to and often spoken of in the same context as electromagnetic waves and electromagnetic fields, is high frequency electric currents. Their ability to heat tissue simulates the effect of electromagnetic waves. Consequently, high frequency alternating currents have their medical application in diathermy (deep tissue heating), and have been erroneously given the name of "ultra-shortwave" (U.S.W.) therapy.

Unlike microwave (M.W.) therapy also used in medical diathermy, "ultra-shortwave" therapy has nothing to do with short waves but utilizes ultra-high frequency electrical currents. The commonly used and approved frequency is 27 MHz. One of the two techniques employed is called the condenser field technique in which the target (patient) is a part of the total circuit which conducts the electrical current from the current generator through a capacitor. The second or the inductive field technique involves an alternating current passing through a coil. The subsequent alternating magnetic field in turn causes electrical currents in the conducting body tissues. The extent of the heating of biological material in high-frequency condenser fields is related both to the dielectric constant and to the conductivity of the material. The conductivity at which the maximum effect occurs is proportional to the frequency for a given concentration of the electrolyte. This heating of electrolytes in high-frequency fields has an important bearing upon the extent to which biological specimens are heated when placed in such fields. Biological effects of high-frequency alternating currents have been observed for bacteria and viruses which were totally inactivated when alternating current was passed through the liquid medium below the temperature at which heating effects may occur.

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[2] Professor Emeritus in Biology, Tufts University, Medford, Massachusetts.

[3] Chief, Surgical Neurology, National Institute of Neurological Diseases and Stroke, Bethesda, Maryland.

[4] Acting Chief, Experimental Studies Branch, Division of Biological Effects, Bureau of Radiological Health, Public Health Service.

[5] Acting Chief, Genetic Studies Section, Division of Biological Effects, Bureau of Radiological Health, Public Health Service.

Although some investigators still question the interpretation of so-called nonthermal effects, numerous claims strongly supporting nonthermal interactions between electric and magnetic fields at low frequency exist in the literature.

One of the most significant and consistent athermal effects is "pearl-chain" formation which is most pronounced around 20 MHz. Pearl-chain formation refers to the tendency of microscopic particles to rearrange under the influence of electrical fields, to form chains of particles in the field direction. Particles suspended in a liquid of a different dielectric constant become electrically polarized when they are subjected to a high frequency alternating field. Electrical charges appear on the boundaries of the particle which in essence create an electrical dipole, aligning itself with the electrical field. Particles in close proximity will tend to attract each other, forming the characteristic pearl-chains.

In one study involving the exposure of alcohol dehydrogenase and DNA to very low and radio-frequency fields, no observable structural changes were found (as determined by changes in hypochromicity and viscosity) even though absorption of electromagnetic energy was observable through measurement of dielectric loss. However, a definite athermal chemical change in macromolecules has been demonstrated in another study, in which it was observed that irradiation at 13 MHz produced a component in gamma globulin with a different electrophoretic mobility as well as different immunochemical properties from control gamma globulin. Following low frequency exposure, there have been reports of chromosomal aberrations (linear shortening of chromosomes, pseudo-chiasmata, amitotic division, bridging, irregularities in the chromosomal envelope) in garlic root tips growing in water. The root tips had been placed between two insulated electrodes for five minutes with a pulsed frequency of 27 MHz with no observable changes in water temperature.

Possibly related to pearl-chain formation of particles is the strange behavior of unicellular and microorganisms when exposed to radiofrequency fields. Nonmotile organisms aligned parallel to the lines of force at frequencies in the lower megahertz range, and some of those aligned at right angles to the lines of force at higher frequency. Similarly, motile microorganisms were constrained to travel only parallel to the field at lower frequency (8.5 MHz) and at right angles to the lines of force at higher frequencies.

A sizeable portion of the literature on biological effects of radio-frequency and low-frequency waves has come out of Russia, primarily dealing with functional changes in the nervous and cardiovascular systems. Some of the documented effects which have been categorized as athermal are an alteration in conditioned-reflex activity of the brain of rabbits, and deleterious effects on motor functions.

In the United States, rats exposed to frequencies of 6, 14, and 21 MHz, and 3 levels of radiation exposure have been examined for physiological and pathological changes. The physiological parameters that were studied consisted of water consumption, fecal count, weight change, and intestinal motility. Although there were differences between the various groups and their controls, changes were not consistent and clear-cut. More conclusive were the findings of pathological effects derived from analysis of autopsies during irradiation and post-irradiation. The pathological effects were based on studies of the cardiovascular, respiratory, hematopoietic, gastrointestinal, genitourinary, and endocrine systems. All but the endocrine system showed significant effects of the irradiation over the control.

There is sufficient evidence in the literature indicating that electromagnetic radiation in the radio-frequency and very-low-frequency range is capable of producing thermal effects which are, therefore, absorbed dosage dependent as well as nonthermal effects which are field dependent and not necessarily related to heating. These effects are primarily concerned with pearl-chain formation, central nervous system, and peripheral nervous system.

Other Radiations

Having covered the entire electromagnetic spectrum, and that only superficially, there remains such topics as magnetic fields and the sound spectrum.

In the case of intense magnetic fields, there have been a considerable number of biological effects observed from exposure to high intensity fields. This, however, is not a problem which could affect significant numbers of people and, therefore, no further discussion is necessary.

In regard to the sound spectrum, there does appear to be a need for some concern for products which emit ultrasonic energy.

Summary Report on the Biological Effects of "Ultrasonic" Energy

With the increasing use of ultrasonics in diagnostic and therapeutic medicine, in industry,and in biological research, those who are public health oriented should prudently examine the possibility of ultrasonic energy being a public health problem.

The use of ultrasonics in medicine in the diagnosis and treatment of human ailments has become widespread. For example, several thousand cases per week are involved in the United Kingdom. However, no evidence of any harmful effects after several hundred obstetric and gynecological examinations has been reported. Also, no changes in EEG patterns, cerebral tissue enzyme, and histology have been found in the brains of six terminal patients exposed for periods of one hour each to diagnostic pulsed ultrasonic energy. Emphasis should be made of the fact that no long-term follow-up studies have been done on those receiving ultrasonic energy for medical purposes.

In animal studies using diagnostic-type ultrasonic irradiations, no detectable genetic changes after irradiating frog spawn have been found. Similarly, in a more extensive investigation on mice, no toxic, histological, behavioral or genetic changes following exposure to ultrasonic energy were found. However, one investigator does report that higher intensity pulsed exposures of pregnant mice produced a significant change in litter size and a concomitant increase in fetal abnormalities.

Summary

In summary, several points can be made:

1. The available information on the biological effects of nonionizing radiation is difficult to interpret as to its meaning to public health problems. Many contradictions exist.

2. This difficulty in interpretation can be overcome only by a research effort well-designed to answer specific questions.

3. The research effort into the biological effects must be equalled by an effort in the dosimetry aspects of these problems.

4. Some of these areas, because of their difficulties and uncertainties, offer tremendous and exciting opportunities to scientists in radiation activities to make a significant contribution to public health information.

I would make one final comment, which is rather personal. I have been in ionizing radiation for 17 years and, as a physicist, became interested in biological systems. To me the microwave area of research is extremely exciting; it is exciting for the physicist to be able to measure this form of radiation; and it is exciting to a biologist because so much uncertainty still exists as to the effects of this form of radiation.

I think in the next few years there will be a great deal of effort put into the investigation of the microwave region and also the region below the microwave. This is an exciting field, and I know many of you will come into this field as excited as I am.

DR. MILLER: Thank you, Bill, for that excellent overview in such a short period of time.

Mr. Charles Weaver will give you an insight on surveillance problems. I think it is a very timely discussion.

SURVEILLANCE IN PERSPECTIVE

Charles L. Weaver[1]

The environmental surveillance activities by both Federal and State health agencies in the past have been carried out in relation to fallout from atmospheric nuclear weapons test activities to determine the radioactivity in air, milk, water, and food. In 1962, the Nuclear Test Ban Treaty was negotiated. In the years following the treaty, the levels of radioactivity in the environment have decreased annually until the levels in the principal vectors appear to be constant with respect to the critical nuclides of strontium and cesium.

Periodically, China and France, who are not signatory to the Test Ban Treaty, conduct atmospheric tests which result in short-term intrusions of radioactivity that can be detected by surveillance networks. However, recent megaton tests by China have not been detected, and I think this is rather significant. It shows a change in the design of the nuclear weapon.

The fission products released into the atmosphere as a result of atmospheric tests by both France and China, and nuclear crater experiments by the United States, have been reduced due to the improved design in the test device. These designs have changed the fission-to-fusion ratio to the extent that there is now a greater proportion of fusion to obtain the desired yield; consequently, the tests have released to the environment a greatly reduced amount of fission products. In reviewing the data from tests conducted since 1962, there has been a verification of reduction in fission products. In planning for surveillance activities in the future, health agencies must be aware of the changes in the international situation related to the Test Ban Treaty, and the Nuclear Non-Proliferation Treaty.

The years ahead will bring increased uses of atomic energy for the generation of electric power, for research, for many industrial applications, and for ship propulsion. The uses of nuclear explosions for peaceful purposes are just beginning and may become important in future years, as will the uses of nuclear power in outer space. Small electrical generators that utilize the decay heat of selected radionuclides are already serving in outer space and in remote terrestrial locations where they provide the power for weather observatories and navigational aids.

The use of radioactive isotopes as tracers for study of the atmosphere, hydrosphere, and biosphere has, in the past, been restricted almost entirely to the use of naturally-occurring nuclides and radioactive substances that were dispersed in the environment by nuclear weapons testing programs. There is much to be gained from environmental studies utilizing radioactive tracers, and deliberate releases for such purpose can be justified in many situations, subject to careful review by regulatory bodies.

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[1] Director, Division of Environmental Radiation, Bureau of Radiological Health, Public Health Service.

National Policy for the Environment

Now, from here I thought we needed to look to whom we normally are going to go for guidance in these troubled times, and that is to our Congress. I found there had been a Joint House-Senate Colloquium to Discuss National Policy for the Environment held on July 17, 1968, by the Committee on Interior and Insular Affairs of the Senate and the Committee on Science and Astronautics of the House of Representatives. At this hearing, a draft of the elements of a national policy for the environment was developed. The language suggested for the statement of policy can be used for the guidance of State and local governments in developing their individual action plans. This suggested policy is as follows; however, it has not yet been adopted:

> "Environmental quality and productivity shall be considered in a worldwide context, extending in time from the present to the long-term future.
>
> Purposeful, intelligent management to recognize and accommodate the conflicting uses of the environment shall be a national responsibility.
>
> Information required for systematic management shall be provided in a complete and timely manner.
>
> Education shall develop a basis of individual citizen understanding and appreciation of environmental relationships and participation in decision making on these issues.
>
> Science and technology shall provide management with increased options and capabilities for enhanced productivity and constructive use of the environment."

At these hearings, also, statements were made by Dr. Philip Lee, Assistant Secretary for Health and Scientific Affairs, Department of Health, Education, and Welfare. He stated that:

> "The Federal Government cannot, and should not, be expected to have total responsibility for these efforts. State and local government, industry, the scientific community, conservation and health organizations, and the general public must all be involved.
>
> Among the activities in which the Federal Government should play a prominent role are: (1) the development of goals and broad national leadership; (2) the conduct and support of necessary research and development; (3) the extension of both

> technical and financial support to States and local governments in their essential functions in this field; (4) the encouragement of State and local control efforts; and (5) the exercise of regulatory authority where State or local action is either ineffective, inadequate, or inappropriate."

Further, he stated that the first responsibility for carrying out a program of environmental quality enhancement rests with State and local governments.

That is, I think, a summary, if I interpret it broadly, a chart for this working group.

Bureau of Radiological Health Surveillance Networks

In February 1969 the surveillance networks operated by the Bureau of Radiological Health, Division of Environmental Radiation, were reviewed and adjustments in sampling frequency and types of analysis were made to take into consideration the existing national levels of fallout. These networks were established and are operated on the basis of the Presidential Directive of August 1959, which directed the Department of Health, Education, and Welfare, to intensify Departmental activities in the field of radiological health.

The Department was assigned responsibility within the Executive Branch for the collation, analysis, and interpretation of data on environmental radiation levels such as natural background, radiography, medical and industrial uses of isotopes and X-rays, and fallout. The Department delegated this responsibility to the Bureau of Radiological Health, Public Health Service.

In carrying out the intent of this directive, the Bureau of Radiological Health, in its budget submission to Congress each year, has identified measurement and surveillance as a line item under Direct Operations. In the Fiscal Year 1969 Appropriation Hearings, funds in the amount of $4 million were requested. Within this budgeted amount, approximately $300,000 was programmed for the air, milk, and food environmental surveillance networks. And I add, this does not include overhead; it is only the direct operating money that is expended to operate the networks.

The environmental surveillance networks for air, pasteurized milk, and institutional total diet for Fiscal Year 1969 and continuation through Fiscal Year 1970 are summarized in Table 1.

These surveillance networks are considered to be responsive to the changes in the levels of radioactivity from intrusion due to tests by China or from nuclear cratering experiments at the Nevada Test Site. The stations were established to provide data on radioactivity on a nationwide basis and not necessarily to detect radioactivity from specific sources. The Radiation Alert Network detected increased levels

Table 1. Environmental Surveillance Networks

Network[1]	Number of Stations	Frequency of Analysis	Specific Analysis Performed
RAN	73	Daily	Gross B, Pu, ^{3}H
PMN	63	Weekly	^{137}C, ^{140}Ba, ^{131}I, ^{14}C,
		Monthly	^{90}Sr
ITDSN	29	Monthly	Ca, K, ^{137}Cs, ^{140}Ba, ^{131}I, ^{89}Sr, ^{90}Sr, ^{226}Ra, ^{14}C

[1] RAN Radiation Alert Network
PMN Pasteurized Milk Network
ITDSN Institutional Total Diet Sampling Network

of radioactivity following Project Schooner, a nuclear cratering experiment, conducted at the Nevada Test Site on December 8, 1968. The data obtained from this network were used by both the Atomic Energy Commission and the Public Health Service in responding to Congressional inquiries and requests from the news media for information on the fallout from this event. The Public Health Service was able, because of our ability to rapidly change the sampling frequency of the RAN, to provide data in less than 24 hours following the event.

In order to carry out the Bureau's commitments to Congress for measurement and surveillance, a periodic review of the networks is required to determine if they are being operated in a manner which provides adequate data to meet the current and projected needs from a Federal standpoint. It is possible because of the changing national situation and the improvement in weapons design that further modifications of these networks will be required. The modifications of the Federal networks are consistent with the Presidential Directive and the Bureau's commitment to Congress. This judgment is based on the interpretation of these directives as they apply to radiation surveillance operations.

The Future Potential for Environmental Radiation Exposure

The environmental surveillance activities needed to measure sources of environmental radioactivity must now be directed toward those specific sources of radioactivity that are being developed and promoted by the nuclear industry. The Environmental Radiation Exposure Advisory Committee of the Bureau of Radiological Health recognized this problem and developed a report entitled "Environmental Contamination by Radioactive Substances" dated December 1, 1967. On pages 7 through 12 of this report, the future sources of environmental contamination were discussed as related to Federal and State radiological health programs. The potential sources are:

- nuclear reactors
- reprocessing plants
- transportation of radioactive material
- nuclear powered ships
- peaceful uses of nuclear energy
- nuclear weapons testing
- aerospace applications
- radioisotope applications
- radioactive waste management
- other potential sources of exposure

It is the responsibility of both Federal and State health agencies to review these potential sources of radioactivity and develop by working together environmental surveillance programs that will have the capability of detecting releases from these sources. In essence, this means that surveillance activities should now be source oriented rather than solely for the purpose of detecting fallout from weapons test activities. It is recognized that this type of surveillance activity will tend to reduce the level of effort by the Federal Government on a nationwide basis and increase the surveillance activities by individual States that have potential sources of environmental contamination from nuclear facilities.

State Versus Federal Networks Surveillance

One of the purposes of this workshop is to review State and Federal surveillance networks and develop recommendations for their respective roles. The present surveillance activities of the States and Bureau of Radiological Health are summarized in Table 2.

Federal and State health agencies looking at surveillance in perspective must both be cognizant of the need for an increased role by State health departments. Thus, a plan must be developed to establish the roles of both agencies and concomitantly continue to provide for the adequate surveillance of radioactivity and for collation of the data in a format that will provide nationwide coverage.

In my judgment, a five-year program must be developed to provide for increased responsibility on the part of each State for the assumption of surveillance activities. The role of the Federal Government under this plan should be to stimulate the States in their environmental surveillance activities and to provide quality control services to assure that the data developed by the individual States are compatible.

This recommendation can be related to the program conducted by the Atomic Energy Commission with respect to the States taking over responsibility for the licensing of byproduct, source, and special nuclear materials. An Agreement State is the term commonly used in referring

Table 2. Summary of State Surveillance Activities

State	Air	Milk	Water	Diet	Miscel-laneous	Nuclear Facilities
Alabama	X	X	X	O	O	O
Alaska	O	O	O	O	O	O
Arizona	O	O	X	O	O	O
Arkansas	X	X	X	O	O	O
California	X	X	X	X	X	X
Colorado	X	X	X	O	O	O
Connecticut	O	X	X	X	X	X
Delaware	O	X	X	O	X	O
Dist. of Col.	O	O	O	O	O	O
Florida	X	X	X	O	X	O
Georgia	X	S	X	O	O	O
Hawaii	X	X	X	O	O	O
Idaho	X	X	X	O	O	O
Illinois	X	X	X	O	O	O
Indiana	O	X	X	X	O	O
Iowa	X	X	X	O	X	O
Kansas	O	X	X	O	X	O
Kentucky	X	X	X	O	X	O
Louisiana	O	X	X	O	X	O
Maine	O	X	X	O	O	O
Maryland	X	X	X	O	X	O
Massachusetts	X	X	X	O	X	X
Michigan	X	X	X	O	X	X
Minnesota	X	X	X	O	X	X
Mississippi	O	O	X	O	O	O
Missouri	O	O	X	O	O	O
Montana	S	O	O	O	O	O
Nebraska	X	X	X	O	O	O
Nevada	X	X	O	O	O	O
New Hampshire	X	X	O	O	X	O
New Jersey	O	X	X	O	X	O
New Mexico	O	X	X	O	O	O
New York	X	X	X	O	X	X
North Carolina	X	X	X	X	X	X
North Dakota	X	X	X	O	O	O

Table 2. (Continued)

State	Air	Milk	Water	Diet	Miscel-laneous	Nuclear Facilities
Ohio	O	X	X	O	O	O
Oklahoma	O	X	X	O	O	O
Oregon	O	X	X	O	X	O
Pennsylvania	O	X	X	O	X	X
Puerto Rico	X	X	X	O	O	O
Rhode Island	X	O	X	O	X	O
South Carolina	X	O	X	O	X	O
South Dakota	O	O	O	O	O	X
Tennessee	O	X	X	O	O	O
Texas	O	X	X	O	X	O
Utah	X	X	X	O	X	O
Vermont	X	X	O	O	O	O
Virginia	O	X	X	O	X	O
Washington	O	X	X	O	X	X
West Virginia	O	O	O	O	O	O
Wisconsin	X	X	X	O	X	X
Wyoming	O	O	X	O	X	O
TOTAL 52%	28(54%)	41(79%)	44(85%)	4(8%)	26(50%)	11(21%)

X Active Program
O No Program
S Standby Program

to the take-over by the States for this activity after the State has demonstrated its capability for conducting the program and that the program is compatible with that of the Atomic Energy Commission. A similar type arrangement could be negotiated with each State for the assumption by the State of environmental surveillance for radioactivity in air, milk, and food.

Under this plan, each State, based upon a program evaluation and in technical discussions with the Bureau of Radiological Health, could develop an agreement for these responsibilities. By this means, each State that has an adequate program could assume a responsible role in the measurement of radioactivity for specific sources of radioactive environmental contaminants and for continued assessment of the levels from worldwide fallout. Arrangements would be made under terms of the agreement for publication of State surveillance data together with Federal data in the Bureau publication, Radiological Health Data and Reports.

For those States which do not have the capability for environmental surveillance, a Bureau of Radiological Health program would continue in these States for a period of time until it is determined on the basis of the radiological situation that there is no longer a requirement for the surveillance activities. It is believed that an active program to stimulate the States to take over this responsibility is needed at this time in order to place environmental surveillance in proper perspective.

DR. MILLER: Thank you, Chuck, for an excellent review of environmental surveillance requirements.

It is my pleasure to introduce our next speaker, the Commissioner of the Environmental Control Administration, Mr. Chris Hansen.

THE ROLE OF STATES AND REGIONAL OFFICES IN THE CONTROL OF RADIATION

Chris A. Hansen[1]

I am particularly happy to be here today to talk about the role of the States and regional offices in the control of radiation. I feel rather deeply on this for a number of reasons, having worked for the State and local health departments for quite some years in Georgia. As a matter of fact, I spent a good deal of time going from Georgia to other places and working in the State of Alabama and a number of other Southern States. I feel that we have a very difficult job to do here and a real cooperative effort by the States, the local governments, the local agencies, and the central government is absolutely essential.

In any situation where the public health and safety may be jeopardized, all parties--industry, commerce, the Federal Government, the State and local governments, and the individual--must take into account the public interest. Many years ago the principle of protection of the public against fraud and deception in advertising was established. Many of you will recall the journalist muckrakers in Theodore Roosevelt's day, who demonstrated that the power of public opinion can change public policy.

The thrust of public opinion and of Congressional feeling regarding consumer protection and environmental control during the past several years has been clear, too. In air and water pollution, in product safety, in automobile and highway safety, and in many other fields, the Nation is advancing at a very rapid pace, determined by both technology and possibly more importantly, public demand. An interesting principle is involved in each of these areas, and this principle is the health, safety, and the common good of the public must be protected.

Sometimes, through a voluntary process, industry acts to provide that protection. When detergent foam presented major hazards to our streams, lakes, and underground water supplies, the soap and detergent industry, you might recall, developed biodegradable detergents to correct the problem so legal action wasn't necessary. Obviously, it was essential to their economy also.

In many cases, however, the market mechanism does not exert enough force, or the right kind of force, or the resources of private enterprise are insufficient to provide the protection the public deserves and in most cases demands. We accept the principle of protection of the public by public agencies in many areas such as health and sanitation, food and drugs, meat inspection and grading, aircraft safety, hazardous substances, agricultural pesticides, deceptive trade practices, and, of course, radiological health.

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[1] Commissioner, Environmental Control Administration, Consumer Protection and Environmental Health Service, Public Health Service.

I am firmly convinced that the public interest in radiological health can best be met by a cooperative effort by the State and local agencies and the Federal Government. Our precedents are many, and they go back all the way to the day of Alexander Hamilton, who, in The Federalist Papers, wrote: "Upon the same principle that a man is more attached to his family than to his neighborhood and to his neighborhood than to the community at large, the people of each State would be apt to feel a stronger bias towards their local governments than towards the government of the Union; unless the force of that principle should be destroyed by a much better administration of the latter."

So you see, Hamilton was calling not only for local control, he was calling for effectiveness. In radiological health today, we must strive for control that is closest to the people, providing it is effective, and effectiveness is measured on the local level, by your constituents and mine.

Not many years ago, we were all concerned mainly about population exposure from nuclear fallout and medical and dental X-rays. As long as those sources continue to present even a potential threat, both State and Federal radiological health authorities will continue to be concerned about them. The fallout hazard has been made negligible by the atmospheric Test Ban Treaty. But diagnostic X-ray remains a significant source of exposure for the public. We cannot be complacent, for we have not yet done everything possible to build exposure protection into X-ray machine designs. We are, however, making progress. We know what design improvements need to be made. The X-ray equipment industry, generally speaking , is beginning to make these improvements.

Looking ahead a little further, we can anticipate the day when improvements in equipment and techniques will provide substantial protection for the public. X-ray machine collimators, properly used by trained technologists, will make it possible to restrict the beam to film size or smaller. Eventually, that degree of restriction may be universal. When it is, the American people will receive only about 40 percent of the genetically significant radiation dose they are now estimated to receive annually from diagnostic X-ray.

Within a few years, if prudent preventive measures are not continued and strengthened, I expect nuclear energy in its peaceful uses to supersede diagnostic X-ray as the largest single man-made source of radiation reaching the United States population. I base my expectation on the further growth of nuclear energy, which is rapidly becoming a major source of United States electric power.

We are entering a new era in radiological health. Local, State, and Federal health authorities are responsible for surveillance in the vicinity of nuclear reactors, for surveillance of contamination of the environment by tritium, krypton-85, and other radioactive materials. For all of us in radiological health, this source-oriented surveillance will be a major responsibility. If effective controls are not administered, in a few years it may be the major responsibility.

Public health people, meanwhile, are concerned with, and responsible for, the population exposure implications of three trends: (a) the growing use of radioactive materials in research, industry, and in the diagnosis and treatment of disease; (b) the proliferation of radiation-generating electronic equipment in research, industry, and the home; and (c) the expanding use of radiation sources in entirely new applications in the plant or the laboratory, as needed.

Not only are the sources of radiation proliferating, but the environments in which people are exposed are changing rapidly, and consequently the numbers of persons exposed are growing rapidly. Lasers are being found increasingly in plants of all sizes. Microwave ovens for the home are expected soon to be produced in quantity. Color television sets are so reasonably priced that millions can afford them. Electronic equipment, including lasers, are moving into the classroom from the junior high school to the university level. Some children are buying them for use in the home, as a toy.

Now what about the changing roles of governments? You might say that we already have entered a new era in radiological health. It is an era marked by changes in responsibilities and authority under Federal law no less striking than changes in the kinds of radiation sources which command our attention. Until a little more than five months ago, all the Federal Government could do in radiation control was prescribed principally in two sections of the Public Health Service Act. The Government could conduct a wide variety of radiation research. It could provide technical assistance to States in the development and conduct of radiological health programs. It could maintain surveillance of environmental radioactivity levels. It could operate broad training programs. It could provide a wide variety of other radiological services. But it had no authority whatsoever to issue or enforce regulations.

We entered into a new era last October 18 when the President signed the Radiation Control for Health and Safety Act of 1968. This is the most important Federal law in radiation control since the Atomic Energy Act of 1954. It authorizes the Secretary of Health, Education, and Welfare, to establish and administer standards for the control of radiation from electronic products on a product-by-product basis whenever he determines that such standards are necessary for the protection of public health and safety. This act constitutes the first action taken by Congress for the exercise of Federal authority in the control of radiation other than authorities vested in the United States Atomic Energy Commission. The evidence is clear on another point: The Congress and the American people recognize the health hazard potential of a broad range of radiation-producing equipment not associated with the utilization of nuclear energy. The act covers electronic products of all kinds which are capable of emitting ionizing or non-ionizing electromagnetic or particulate radiation. Products which may emit sonic, infrasonic, or ultrasonic waves resulting from the operation of electronic circuits also are covered by the new law.

Industry, for its part, is required to take specific actions to comply with standards to be established under the law. The first such standards must be prescribed prior to January 1, 1970. Authority under the law has been delegated to the Commissioner of the Environmental Control Administration. I, in turn, have delegated responsibility for day-to-day administration of the law to the Director, Bureau of Radiological Health.

Now, as to the role of the States, the other speakers at this conference have covered, or will cover, the specific details of plans for implementing the Radiation Control Act. I want to assure you at this point that Doctor Raymond Moore and our entire staff at Environmental Control Administration regard this conference as vital in the development of a partnership in radiological health. Out of your deliberations here will come a document which, after further discussions with your respective health officers, we can rely upon as a major resource in defining our common program needs and methods of achieving them.

In implementing the program, we will require a variety of data for policy development and decision making. Much of this information is available only from the States. I know that you will cooperate by making it available as you have cooperated with us in the past. For our part, we pledge to make the sum of the information available to each of you.

Now, upon the role of the Environmental Control Administration regional offices, your new responsibilities will place new requirements, and perhaps new burdens, on you. You will, therefore, need some help. Historically, assistance to the States from the Public Health Service has been provided through our regional offices. I expect this system to continue, and in fact the Radiation Control Act gives us a fresh opportunity to make our regional operations more responsive to the States' needs.

As Environmental Control Administration is new, some of you may not be familiar with our operations. The Environmental Control Administration has just over 100 persons assigned to the nine Public Health Service regional offices. Sixty-six of these are professionals. These men are responsible for the review of model cities proposals, the review of comprehensive health plans and other projects such as Appalachia in Region III, and for all other Environmental Control Administration program interests. They will participate in development of plans and programs for grants in radiological health, solid waste management, rodent control, housing and urban sanitation, water hygiene, and other fields. They are supported by our research staff and the headquarters staff in Rockville. And we are considering establishing a cadre of troubleshooters to be available to the regional offices for emergency duty.

I am represented in each regional office by a Regional Environmental Control Director. Under him, is a program man for, say, the Bureau of Radiological Health. This man is your contact between your State and my office. He is the clearinghouse for technological informaation. He is responsible to me for moving information in both directions. He is available as your consultant in establishing compatibility of programs between the various States and between States and the Federal program. The Regional Representative is our principal information gathering source. He acquires data needed for planning and evaluating the effectiveness of nationwide control mechanisms and for developing the periodic reports to Congress and the Department required by the act. The regional office will continue to respond to the specific needs of individual States, and, since State agencies should have responsibilities in the development of performance standards and the evaluation of potential hazards from electronic products, the regional office mechanism will be utilized as the primary contact point for this activity.

There is one other matter which I am certain you are all very much interested in. The Radiation Act authorizes the Secretary to make grants or to enter into contracts for the purposes of establishing and carrying out an electronic product radiation control program. It is our intention to use this authority for joint projects with the States, if and when financial support becomes available.

A major part, work under way in radiological health prior to the enactment of the radiation law, will continue at the same time that we assume new responsibilities. However, some reprogramming will be necessary, particularly since we are not adequately funded to carry out the total responsibility required by the new legislation. We will expand our research efforts in electronic products, in radioactive materials, and in radiation health effects, and we will expand our training program, as we feel that training is essential to the improvement of public health protection against radiation hazards.

Our charge comes not only from the Congress but also from the Department of Health, Education, and Welfare. Soon after he assumed the post as Secretary, Mr. Robert H. Finch described the Consumer Protection and Environmental Health Service as having been "established to provide a single agency in the Federal Government able to take a broad view of our environmental and related consumer problems."

Finally, our charge comes from the public, the consumers. You are all familiar with the public demand for controlling pollution and for improving the environment. An article in the March issue of *Fortune*, entitled "We Can Afford a Better America," declares, "The nation must correct the savage deterioration in the lives of *all* who breathe the air, ride the highways, crowd into cities, and spill out into suburbs."

Perhaps the most important question one can ask is, "Can we afford the necessary steps?" *Fortune* thinks so, concluding, "During the next decade, economic growth will make available plenty of money to do what needs doing." I would add that we, as State and Federal officials, hold the responsibility for protecting the public interest to the best of our ability, using available and new technology. To the extent that we perform well, the Congress and the public will support our efforts.

DR. MILLER: Thank you, Mr. Hansen, for your timely remarks.

For a review of the diagnostic X-ray problem, Dr. William Cole will present a paper by Dr. Richard McDowell.

THE DIAGNOSTIC X-RAY PROBLEM IN THE UNITED STATES

Richard B. McDowell, D.D.S.[1]

Presented by
William S. Cole, M.D.[2]

Presently, the estimated 210,000 X-ray machines used in the healing arts constitute one of the major man-made sources of radiation exposure to the general population. At the present time, more than one half of the population of the United States undergoes a diagnostic X-ray procedure yearly. The 1964 Public Health Service X-ray Exposure Study estimated that there were over 143 million X-ray visits yearly--50 million dental and 93 million medical. Involved in these visits were an estimated 506 million films or exposures.

Considering these data and a 5.4 percent average compounded rate increase in medical X-ray film consumption, one can appreciate the potential for unnecessary exposure from the use of X-ray by practitioners of the healing arts. We have identified three major problem areas that are contributing to the unnecessary population exposure. They are: (1) the continued use of X-ray equipment that does not meet accepted recommendations; (2) the use of equipment by operators who are not competent by training, experience, or knowledge in the use of the more advanced techniques; (3) the use of X-rays in an injudicious, repetitive, and ineffective manner.

It is our opinion that considerable progress has been made during the past few years in attacking the problem of unnecessary population exposure. This progress is significant in light of the March 1959 report to the Surgeon General prepared by the National Advisory Committee on Radiation Protection entitled The Control of Radiation Hazards in the United States, which pointed out the need for a comprehensive radiation control program that should be shared by the Federal, State, and local governments.

For example, the man-year equivalents (full- and part-time) engaged in State X-ray survey and control activities have increased from a reported 74 to 150 man-year equivalents between Fiscal Year 1962 and Fiscal Year 1967. During this same time, the number of States having regulatory or compliance type programs progressively increased to the point that, by the end of Fiscal Year 1967, 26 of the 53 State X-ray programs were classified as being regulatory in nature. The remaining were either voluntary or a combination of voluntary and regulatory.

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Accompanying the development of State programs there has been a significant reduction in the use of X-ray equipment that does not meet present recommendations or standards. For example, if one reviews the results of dental surveys conducted prior to 1960, it is revealed that approximately 60 percent to 80 percent of the units did not meet the present recommended standards for filtration and collimation as proposed by the National Council on Radiation Protection and Measurements. Today, however, we can reasonably estimate that greater than 80 percent of the estimated 100,000 dental X-ray machines in the United States now meet minimal standards for filtration and collimation.

Unfortunately, progress in the correction of deficiencies in medical or medical-type installations has not been quite as dramatic as that experienced in the correction of dental X-ray machine deficiencies. In part, this was due to the ease in which the dental X-ray machines were corrected and to a delayed interest or emphasis on medical X-ray surveys on the part of most States. In 1963, the various reporting agencies estimated that there were between 100,000 and 125,000 medical X-ray machines in this country, of which approximately 45,000 had been inspected or surveyed at least once. Of that number, it was reported that 50 percent to 90 percent of the machines surveyed did not meet State recommendations or standards. By June 30, 1967, approximately 45,000 of the estimated 112,000 medical X-ray machines currently in use by non-Federal practitioners in the healing arts were reported to meet current State recommendations or standards.

From this, we must conclude that the equipment problem is not yet solved and that considerable effort will be necessary to bring the remaining medical X-ray installations up to minimal recommendations or standards. Once a reasonable compliance percentage is assured, increased emphasis must be placed on improving the qualifications of the operators and on the efficient, effective, and judicious use of the equipment. The potential audience for this effort involves approximately 400,000 practitioners in the healing arts and an estimated 300,000 X-ray machine operators.

X-ray Equipment

Before we go on to the problems of technique and judgment, let us look more closely at this problem of the continued use of X-ray equipment that does not meet recommendations or standards. By the end of Fiscal Year 1967, only 26 of the 53 radiological health programs had reasonably rigid equipment regulations. In general, the majority followed the recommendations of the National Council on Radiation Protection and Measurements or the suggested State regulations proposed by the Council of State Governments for the control of radiation.

Unfortunately, however, there does not appear to be a uniform or reasonably uniform application or interpretation of these recommendations or standards. In part, this can be attributed to the various program philosophies, the lack of standardization of surveyors and/or survey techniques, inexperience on the part of the surveyor, and the use of recommendations that are not current with respect to those presently proposed by the National Council on Radiation Protection and Measurements or the Council of State Governments. In addition, there is a reluctance on the part of some State programs to identify and investigate causes of unnecessary or unproductive radiation exposure beyond those specified by their rules or regulations. Examples include timer accuracy and reproducibility, poor film-screen contact, deteriorated screens and the accuracy of adjustable collimators. From this, it seems that an increased effort will be required in the development of standards and regulations that cover all aspects of equipment and accessories used in the radiographic process.

Therefore, if we are to achieve the goal of obtaining the maximum amount of information per unit of radiation exposure, we must continue our efforts to upgrade X-ray facilities and in addition place more emphasis on the areas of technique and judgment.

Operators

The second major problem area we have identified is the use of equipment by operators who are not competent by training, experience, or knowledge in the use of the more advanced techniques. In this area, we can identify such factors as the proper selection of patient position and machine settings, choice of film-screen combinations, proper film development, including darkroom management, and the adherence to current acceptable reduction practices such as gonadal shielding and the collimation of the primary beam to the clinical area of interest.

The ultimate solution to this problem will be obtained only when all of those who operate X-ray equipment, including licensed practitioners, employ the most efficient techniques, thus attaining the optimum clinical result per unit of radiation exposure for both the patient and the operator. But what should be the minimum qualifications for X-ray machine operators? This question alone promotes considerable discussion when one considers factors such as, "Is it necessary that an operator using an X-ray machine for a single purpose have the same qualifications as one who is involved in performing many varying types of examinations on a multi-purpose machine?"

New York State, for example, requires the licensing of all X-ray machine operators except those nonprofessional individuals who are using X-ray for dental diagnostic purposes, in which case the primary beam must be limited to an area no greater than three inches at the patient's face. Oregon, on the other hand, requires a Certificate of Radiological Proficiency for all dental assistants who operate X-ray machines. Yet, there is no provision in the Oregon law for the licensing of nonprofessional operators of medical-type equipment.

Therefore, if one were to establish categories for operators, what criteria should be used for each category with respect to training and experience? Is it necessary that the operator be a graduate of an a accredited school, or are there other criteria that need to be defined to determine operator qualifications?

A study conducted by the Division of Radiological Health in 1966 showed that approximately 95 percent of the part-time nonregistered medical operators had no formal X-ray training whatsoever, and that 86 percent of this group were employed in private offices and clinics. Although their workload was relatively low when compared with the registered operators, this group represents about one half of the machine operators in medicine, excluding the licensed practitioner.

To eliminate this situation, we feel that a minimum standard of experience and training should be established for all operators of X-ray equipment. Once this is a reality, training materials and standardized course material applicable to X-ray protection practices within the various healing arts professions can be developed. These can be used to promote a standard curriculum so that a minimum knowledge requirement will be possessed by all X-ray machine operators. In any case, we must be certain that the operators of the machines are competent and are using the most advanced techniques available so as to insure the maximum amount of benefit per unit of radiation exposure.

Judicious Use

The last problem area that has been identified perhaps will prove the most difficult to solve. This is the judgment area involving the decision to use X-ray for specific diagnostic purposes. The prime target group in this instance is the practitioner, including those in voluntary and governmental public health agencies, who are responsible for determining whether a specific procedure should be conducted in order to promote the health of the individual patient or group of patients.

For example, one frequently sees repeated mass X-ray screening techniques used in geographic areas where the incidence of new cases of active disease is traditionally low. In many cases, these examinations are conducted with equipment that use inefficient lens systems when compared to the more modern mirror optic systems. Similarly, upright fluoroscopic machines are currently being used for chest radiography, and pediatric fluoroscopy is still performed on unamplified fluoroscopes.

To influence the judgment of the practitioner, however, will not necessarily mean an overall reduction of radiation exposure, but rather it will help assure that the greatest diagnostic benefit is obtained from the specific procedure or examination. If one orders a particular X-ray procedure, one must assure himself that it is: (1) necessary, and (2) it is done under optimal conditions prevalent to that particular examination.

The question immediately arises--"How do we go about solving this problem?" It would seem that two or three solutions could be identified. Perhaps the most obvious is to introduce into the educational process of preprofessional graduates the philosophy regarding the benefit-risk criteria involved with the use of X-ray. Yet, teaching institutions are constantly faced with the increasing demands upon the student's time with everyone considering his particular program or academic endeavor more beneficial than another's. For this reason, it would seem appropriate to incorporate questions relating to acceptable radiation protection practices on all State and national board examinations. If this is done, it will require the respective schools to consider this topic as part of their normal curriculum.

In addition to the students' education, efforts must be made to educate the practitioners who are currently using X-ray as part of their practice. But, how does one go about educating an audience who is, in many cases, uninformed or disinterested or is resistant to change? Is it through the development and promotion of refresher courses, seminars, audiovisual materials, etc.? Is it through the adoption of a periodic examination process such as has been proposed recently by a Presidential Commission, or is it through the certification of the X-ray machine operators?

It is quite possible that the ultimate solution to this particular problem will be through the operator of the X-ray machine. If adequate experience, training, and/or qualifications are required in order to operate an X-ray machine, the result should be the utilization of good radiological health practices or radiation reduction techniques. For this reason, it would seem that the education of the respective practitioner might be and could be intimately tied to the actions of the respective X-ray operator.

Regardless of what decision is made with respect to any specific question or problem discussed above, the solution to the three problem areas promises to be a tremendous challenge if we are to assure ourselves that: (1) the most advanced techniques are employed by competent operators; (2) equipment meets recommended standards; and (3) when X-ray is used by a practitioner in the healing arts, it is used efficiently, effectively, and judiciously so that the maximum diagnostic benefit is available to all with a minimum of radiation exposure.

DR. MILLER: Thank you, Bill.

Next, Mr. John Villforth, Chief of the Division of Medical Radiation Exposure, Bureau of Radiological Health, will give us an overview on the magnitude and scope of non-AEC controlled radioisotopes in the United States.

THE MAGNITUDE AND SCOPE OF NON-AEC CONTROLLED RADIOISOTOPES IN THE UNITED STATES

John C. Villforth[1]

Since the theme of this meeting is related to Public Law 90-602, radium does fall under "certain studies." Specifically, it states: "The Secretary shall conduct ... a study of present State and Federal control of health hazards from electronic product radiation and other types of ionizing radiation, which study shall include: ... Control of health hazards from radioactive materials other than materials regulated under the Atomic Energy Act of 1954," and in addition, for the Secretary to study "any gaps and inconsistencies in present controls."

Another part under Section 357, which is of interest and which may suggest what may possibly be involved in the future directions of Public Law 90-602, is a suggestion that the Secretary "determine the necessity for the development of standards for the use of nonmedical electronic products for commercial and industrial purposes." This is the first time the Secretary has been directed to look at the user aspect of the problem.

The Act also states that in so looking at those studies, the Secretary is to invite the participation of other Federal departments and agencies having regulative responsibilities and interests, and State governments, particularly those States which regulate radioactive materials under the Atomic Energy Act. Finally, I would like to call your attention to the fact that these studies are not limited to the specific areas called for under Section 357. However, with the resources that are available right now, I think we are going to have enough to keep us busy studying just the specific requirements.

Now it seems rather unnecessary for me to redescribe some of the problems associated with radium. We have been talking about it for the last six years, we have been listening to you describe to us some of the particular hazards and concerns that you have in regard to the control of its use, and some of the apprehensions you have with regard to the sources that are in use.

I do want to point out, perhaps for the record, that radium, although it is the oldest and the most commonly used radioactive material, has certain physical and chemical characteristics which make it somewhat unique. We know that radium is highly toxic because of its complex radioactive decay series, including the emission of radon gas, and the fact that radium behaves chemically like barium, which means that it concentrates in the bone. We know that occasionally salts as bromide and cloride are found in sealed sources, and because they are very soluble and result in the frequent decomposition of the water of hydration which may be in the sources, the buildup of pressure in old sealed sources is something with which to be concerned.

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These are, of course, the physical and mechanical characteristics. As you all have pointed out, there are some other disadvantages with radium; particularly the fact that, up until about ten years ago, there was very little interest on the part of the Federal Government, and a very minimal interest on the part of the States, in attempting to bring radium under some sort of public health control. It was only recently, perhaps with the enactment of the Atomic Energy Amendment, that some States were provided the impetus to get into the regulatory control of radium. We still, of course, have some States that have not launched into this area, and we still find that there are many sources, the use of which is not controlled in some of our States.

In addition to these problems, radium has a certain "charisma" particularly with its use in the medical profession. For example, the older physicians who used radium have not been able to adjust to the use of substitutes like cobalt or cesium, and thus there is resistance to accept the less harmful substitutes for radium. The program we had started several years ago of encouraging the use of substitutes has not moved as rapidly as we would have liked.

Now, the medical problems are compounded by the fact that we really don't have a good understanding of the extent of the use of radium in industrial practices today. In 1963, when we talked about the radium program, and presented a discussion at the American Public Health Association meeting, I think it was Dr. Sam Ingraham who came up afterwards and said, "You are going to have to define the dose that is associated with this to put this into proper perspective." This, of course, would have been a very difficult thing to do, because to launch on a population study program to determine dose, we felt would have been a little too expensive for our resources.

As a result, we launched a program to try to develop a public health approach to the solution of the radium problem. Now, under Public Law 90-602, we find ourselves in a situation where we must present to Congress, by January 1970, a study of the extent of the radium problem. I think it is important that we take the resources that we have, and convert them or direct them to solving the problem. I think this is what most of you have been doing over these past years, in directing your efforts to basically the public health approach to the radium problem.

We are going to continue to broaden our areas of interest by conducting several studies between now and this fall which will give us a better handle on the radium use. Specifically, we have written to the manufacturers of industrial radium sources and manufacturers who make devices in which radium may be incorporated as a check source or a calibrating source, or some sort of an ionization source, to determine the extent of their sales in the United States. We are also going back to review the State radium licensing information that is available through the information published in the Atomic Energy Clearing House. We are also examining the information which we will collect of sources that are registered in non-Agreement States, and will tabulate this information and hopefully come up with a specific estimate of the quantity of radium that is in use.

You will remember that we have estimated in the past that there are approximately 2,000 grams of radium in the United States. This is material that has been imported or produced in the United States over the years. We have estimated that we could probably account for only 300 to 600 grams of this radium, the rest being unaccountable either through disposal or from surplus material, or from material that was just not counted by the State agencies. We are about 70 percent complete on our tabulations, and based on the information, it would appear that the average medical facility possesses about 110 milligrams of radium. Now, if we use this average in the total projected number of medical facilities possessing radium, approximately 2,500, and this information we have collected from your inventory information which you have prepared over the past few years, it would appear that there are approximately 300 grams of radium used in medicine in the United States today. Based on the State data, this quantity of radium would be contained in approximately 40,000 to 50,000 sealed sources.

Recently we completed a contract with the Standard Research Institute, who conducted a study including information on the use of radium brachytherapy. This study indicated that there are approximately 85,000 radium treatments conducted in the United States. It is rather interesting that this number is about the same as the estimate made in the 1930's, which could mean that radium has not increased very much in the 30-some years since. I might point out that 85,000 radium treatments compares with the 33,000 brachytherapy treatments from byproduct material.

In terms of the nonmedical area, we find that the annual State inventory data indicates approximately 1,700 nonmedical facilities have been licensed or registered for the possession of radium or radon. We are again in the process of preparing this information from the Atomic Energy Clearing House data. We estimate there are 70 to 100 grams of radium that could be identified in the industrial applications in the United States. This is just in the Agreement States, and we are going to have to get this from all of the States. The largest quantity of this radium is in the well-logging area. The largest number of industrial sources are in the gauging area, check gauges, gauge indicators, and so forth.

Now, an interesting observation. Some of the preliminary information that we have received from the companies that manufacture certain devices, such as dew-point indicators and vacuum gauges, indicates that very few of the sources that have been manufactured and distributed and are in use in this country are accounted for by our State inventory information. For example, from the Agreement States data we have observed that the Alnor dew-pointer is licensed in 26 installations. The company indicates that there are approximately 10,000 of these devices out in the United States. This might suggest the difficulty that we all have of trying to get a handle on this area of use.

In a report on radium luminous compounds, Wayne Robinson has identified the extent that radium is used in timepieces. The gonadal dose from a wristwatch containing one microgram of radium has been measured and is well documented. For a person who wears such a watch 24 hours a day, this dose will be between 65 millirems and 130 millirems each year, or approximately 65 to 130 percent of the annual gonadal dose from natural background radiation. Therefore, the gonadal dose resulting from the use of radium activated self-luminous timepieces can be a significant fraction of the genetic dose from natural background.

I think the concern of some of us is that, although there are international recommendations on timepieces, very little is being done at our level to see that the radium sources and the manufacturers of these sources meet some standards that can be consistent with the standards of byproduct material under the Atomic Energy Commission control. There are other kinds of luminous devices in component parts, many of which are coming and going in the military system, where I think we have to exert a considerable amount of our influence.

The State and the Federal agencies have to work with the user, educating the user, providing information to see that radium is used in the best way and we have to encourage the use of substitutes where applicable. For example, the International Atomic Energy Agency recommends that radium not be used in any pocket watches. It was not too long ago that the Federal Government almost surplused about 3,000 excess pocket watches containing radium. This could have been embarrassing to the Federal agencies involved.

I think we have to take advantage of the new era that Mr. Hansen pointed out. We are now at the threshold of Public Law 90-602, and we have an opportunity to examine some of the electronic products precedents, and see how they might apply to radium. I would suggest that several of the things that might be considered are:

(1) We could get involved in the study of performance standards for the manufacture of sealed radium sources such as those used in

medicine and industry. I think it is very appropriate in the light of the electronic products areas that radium come under a similar type of regulatory control, particularly at the manufacturer's level. This might be a role for the Federal Government to set these performance standards.

(2) It would seem the manufacture of those items which are consumer products, the wrist watches and the clocks and so forth, might come under examination by the Federal Government, and possibly put under some type of regulatory control.

(3) Although there has been much progress in the control of the use of radium by States, some special assistance might be given to those States which have not so far adopted some type of regulatory control for the use of radium.

We hope, as a result of this get-together and this conference, that some of these ideas might be developed into a work plan for guidance for ourselves and also for the State agencies.

DR. MILLER: Thank you, John. I will now turn the meeting over to my Co-Chairman, Tom Gerusky.

Discussion (entire group)

MR. GERUSKY: I have a personal comment. I don't believe that we in the States have really been telling the Public Health Service what we have been doing over the past few years. I don't think the situation is really as bad as it was painted earlier this morning. I think it is our fault for not giving them the kind of information they have been requesting, and I think we must do a better job in getting them the information they need to give to Congress. The numbers that were previously presented are not realistic. Let's make them realistic and let's show what the real radiation hazard problem is in this country, State by State. We can do it. I look at it as a challenge. On Wednesday afternoon, when our Conference of Radiation Control Program Directors meets, we will probably take this up. To begin with, how can we obtain this information promptly, and how can we get it to the people who need it.

DR. FARMER: We have had a very concerned Radiation Advisory Committee in Oregon for the past six months since the new radiation bill was brought forth. We are concerned that perhaps the other areas of environmental activity have seen what can be done through the radiation program, an effective program in Oregon. Now they have moved into the air and water pollution and other areas, which is the way it should be. It should not be at the expense of radiation control, but this is what it has boiled down to in many States, including Oregon, where we have a high value on livability. So we are in a very tight budget battle with these other activities. My point is, I would hope that the Bureau of Radiological Health people and the people in Washington do not forget that the radiation field still exists. Let me reiterate, we do not want to see the field of radiation suffer in this competition.

MR. GERUSKY: Anyone else?

DR. R. PARKER: If this meeting continues to work, I feel we need to keep the objectives in proper perspective. Let's be honest with ourselves. There are proper roles for both of us in the radiological health program. There are certain activities that can be conducted and carried out most effectively on the Federal level. We have to recognize that the States' role, which we have been doing for many years, is not a uniform and consistent thing throughout the States. There are many variations, so the problem is how to get the States to more closely coordinate their efforts. I interpret from what I have been hearing, that we are not doing the job we should be doing in radiological health.

It is my opinion that across the board, certainly in most States, we are doing the proper job. I know many times I find it difficult to get this information across to our counterparts in other States, and the Federal Government. But to stand by and say we are not doing--or meeting the problem, and that all the Federal Government wants is to get the information, is wrong. As I interpret Dr. Cole's and John Villforth's talk, I don't believe that either one of them meant at all that we are failing in our programs in varying degrees. This is certainly not the case.

I would like to address some specific questions both to Dr. Cole and John Villforth. Just what is your proper interpretation? Just what are you saying? Are you really saying that we, in the States, are falling down on the job, that from here on out all we want to do is set the standards, and you people work for us? John, if that is what you people mean, I think you have got a big battle on your hands.

MR. VILLFORTH: I, in no way, intended to imply that you were falling down on the job. Rather, I think the progress that has been made has been made by you and because of you. I don't know how you read into what I said that we were going to "Federalize" these things.

With regard to forming standards for the manufacture of these types of products, that is, radium in sealed sources, it seems to me that this type of thing is most important to be considered at the Federal level. For example, the control of the manufacture of luminous compounds. This is analogous to the performance standards for the manufacture of products such as color TV, and other types of consumer products involving electronic radiation.

I want to point out very clearly that the solution to the problem is not one just of standards and not one just of regulating manufacturers, either. You remember Dr. Russell Pierce's comments to us over the past years, when he talked about the X-ray problem in terms of the equipment, the technique, and the judgment. This goes for electronic products such as lasers, microwave ovens or what have you. Under Public Law 90-602, we can only make one little dent in radiation exposure reduction right now, and that dent is in the performance standards for equipment.

The business of correcting those defective items that are in use right now, medical-dental X-ray machines, etc.; the problem of the technician; and as Dr. Cole pointed out--and it is a very, very difficult problem--judgment, are all very difficult areas upon which we are going to have to rely on help from you folks. But it seems to me there are some areas where the performance standards for radium could best be done by the Federal agency, and that is the point I wanted to make. The problem of the reduction of unnecessary exposure is a complex one.

MR. SNOW: I would like to invite the States to make use of the medium of Radiological Health Data and Reports to report on the progress they are making in their specific radiological health programs. For example, the States might report data relating to their radiation programs and the improvements they have been able to make over a period of some years. This particular medium is yours to use to your advantage.

MR. HARRIS: As many of you know, I see many faces around the room of people with whom I was associated with as far back as 1951, 1952, and 1953. I have been a little concerned, going back to those days, that some of the history of radiation control has been altered in the past by the Public Health Service. I know that the Public Health Service program really became visible in 1958 with the formation of the Division and it was very active earlier in the game through the work of the radiological health people out of Cincinnati.

But I think we must recognize that the States were busy in radiological health as far back as perhaps 1948 and earlier than that. New York City had public hearings on the shoe-fitting fluoroscope in 1948. The American Conference of Governmental Industrial Hygienists was very active, very early in the game. I must say that, by and large, the shoe-fitting fluoroscope problem has been solved. Very few are still in existence in the United States. I don't think the Public Health Service tailor-made all of this, but certainly the Public Health Service participated later on in the evaluation and distribution of information.

The radium static eliminators were being evaluated very early in the game. The radium dial painters' situation became a great problem very early in 1928 and 1929. I still have a copy of the 1931 draft of New York State regulations to control radiation exposure in radium dial painting plants. A bill was introduced in the New York Legislature in the year 1908 to require that physicians using X-rays be licensed. These things can be documented.

Now, I would make a plea that the Public Health Service's own people here in this room stop knocking the States. I can't help getting the feeling, sitting here with both the State men and the Public Health Service men, that we are not really being partners with the States.

Now, the program doesn't look the way it is beginning to sound, and I think that is obviously why some of the State people have buzzed in the hall about the program. I think the program is a fine program, but the language as it comes out seems to be, "You tell us what information we want, you send us copies of your reports, and you tell us what is happening, and we will put this thing together and present it." Now, maybe this is what we have to do, but there are times I feel that maybe we ought to give the States the opportunity of presenting it. In the Congressional hearings we ought to make sure that you people from the States testify, either as an individual or as a collection of States, and I think that is what the undercurrent is about. I know that there has been a close liaison on the program, and the program covers a wide area, but the feeling is that the State people are not being recognized for what they have accomplished, and they clearly have accomplished a great many things.

MR. WILSON: In 1964 and 1965, I would like to remind you there was some disagreement, and they got in a hassle with the Department over some licensing regulations. At that time we had quite a bit of a problem trying to get our house in order with the Department of Labor, at which time we did. Now, the disagreement started with the agreement. I think we were referred to by the Department of Labor as a six-headed monster for a reason--because we raised quite a bit of stink. I would like to remind those of us involved at that time that we went to the States for help, and I think those of us in the meeting at that time can still recall the testimony that was brought out at that meeting. Yesterday I tried to bring out in a subtle way that we were trying to get the decliners to finally give up sometime, even in a public hearing, because the Public Health Service would not back us up at that time. As a matter of fact, they took a more regal attitude rather than a firm stand with the State. But I think as this meeting progresses, things will begin to take shape.

DR. ELDER: I think there is a little bit of misunderstanding in the terms relating to the Public Law 90-602, which overshadows some of our thinking. The pressures are on us to respond, and it may seem to you that we are cutting you out. In my opinion, this meeting has as its sole purpose to cut you in. I think in our anxiety with our own personnel and budget problems, we have attempted to go a little too fast to meet the deadline.

The law that we are going to discuss in a very few minutes is very specific. It is a law for new products and is not a law for old products. We know that there are many products on the market today. The standards will not hold for these, so the historical problems that we now have are not going to go away. The standards will not apply to these and we are going to have to work together to upgrade them. In terms of helping yourselves and having the resources to support you, we will have the document that will be prepared here. We may be overzealous, but ultimately money is going to have to go back to the States to solve the problem of the old products. The law requires that the Committee* must have a State representative on it. It hasn't been announced, but there are State representatives on the Committee. I think that we are seeing a little bit of John Villforth's pressure to get the information to Congress as to why we need the money. Perhaps we are being overzealous in your behalf, rather than cutting you out. We are looking at two problems, the one that we have today and the problem facing us with the new products, and please separate those. The new law is only for new products.

MR. HANSEN: You know it sounds to me as if there is a communications problem here between the States and us in the Federal Government in discussing how the Federal Government relates to the States and to the problem. I think we all need to be a wee bit less sensitive and a little bit less looking over our shoulders at what happened five years ago, ten years ago, or whenever. Take a look at the problem. I don't presume to be an expert or even well-informed in the field of radiological health as it relates to the detailed workings in the States and local areas--but it is perfectly obvious that there is a tremendous amount of work to be done, and it is going to require the capabilities of the States, the Federal Government and the local areas. It is going to require all of the resources we can put together to get into the nuts and bolts as to what is necessary to get the job done.

I want to talk particularly to one point, from a policy standpoint of the Environmental Control Administration. It is our intention and desire to move the program out to the lowest level where it can be accomplished effectively. I mentioned this in my earlier discussion. Let me repeat it. We are not interested in handling all of the responsibility and gaining whatever benefit there is by operating from the Washington level. This is precisely why I dwelt as long as I did on the involvement of the regional offices. The Federal Government is not always located in Washington. There are nine small representative Federal Governments closer to the States and in a better position to operate on a day-to-day basis with the State staff and State activities.

To carry that a little further, I talked briefly with several of you here about the feeling of oppressive approach of the Federal staff here. I reminded them of discussions which we had with the local people in some seminars during the past summer, and it is absolutely remarkable to me that they said the same thing about the States. They said that the States were ignoring them, were taking all the glory, were not listening to them, were not communicating with them. I see the same situation here and for that reason I am real happy that this meeting comes as early in the program as it does because it gives us an opportunity to talk these things out in detail. However, from a policy standpoint, we are interested in decentralizing to the maximum extent possible. We recognize that within the States, particularly in the radiological health field, we do not have exceptional programs in all fifty States.

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*Technical Electronic Product Radiation Safety Standards Committee.

It is really a remarkable situation when you take a look at the total public health problem we have. Many other programs have little or nothing in the way of a program in the State Health Department, or in whatever State agency is concerned. One of our basic missions is to strengthen the State program by grants. Take solid waste, for instance; we are interested and are now making grants to the States in order to provide the funds for them to build a program at the State level. This, of course, has been a major program in the radiological health program area in years past.

I hope your discussions continue and expand and get to our issues that come out on top of the table, not under the table. I am very well pleased with the development of this situation. I want to assure you who represent the States that we are deeply interested and concerned that you have as strong a program as possible, and that the excellent efforts you have made in the past continue. Where we are able, we are going to support you.

MR. WILMS: I wasn't offended by some of the comments made by some of the Public Health Service people here today. I do feel there is a great deal of improvement needed in many of our States, including ours. Probably there is more needed in some States who don't have a comprehensive radiological health program. I think there is a need for better communication between the various regulatory agencies involved.

Rather than being piqued at the comments that were made, I am in fact heartened by them, as I was by Public Law 90-602. For the first time there is an extra amount of emphasis involving the States. It seems to me that in this Act there is a cognizance that the States exist, that they need to be involved and that they are going to be involved.

I would like to put this all in perspective by seconding the remarks that were made by Mr. Hansen. There have been problems in the past in communications, but they need no longer exist under the present Act, and especially now that we have the makings of a Conference of Radiation Control Program Directors. This should be, and I think can be, an effective forum where our ideas can be mixed with those of the Federal Government.

I would be happy to see machine performance standards on a national scale, so that we don't have to worry about the defects of the machine itself. This would let us concentrate on the real area which would do the most good--the area of use standards where we in the State and local areas can do our most effective job. I make the plea that we begin to use our Conference of Radiation Control Program Directors to the fullest extent, and I have confidence that it will be used.

DR. MILLER: I think this discussion was very worthwhile and very needed. One of the purposes of this meeting was to develop better communications between not only the Federal Government and the States, but between States.

LASER AND MICROWAVE PROBLEMS

D. J. Nelson, Jr.[1], and D. L. Solem[2]

DR. MILLER: Let us go on with the program right now and take a look at the laser and microwave problem. To introduce this subject is Mr. Jack Nelson, Director, Electronic Products Division.

MR. NELSON: Now, since this is going to be a technical discussion primarily, I am going to turn this discussion of laser and microwaves over to one of the people on the staff of the Electronic Products Division who knows a great deal about them. We would like to let you hear about some of the problems we are trying to solve in the electronic products area in terms of the entire electromagnetic spectrum. I hope tomorrow, and perhaps this afternoon, I can try to answer your questions as to where we think the best direction is to go with respect to this whole new area. We have certain problems of units and standards and are learning a whole new vocabulary, as are many others.

It is a real pleasure to see a great many of you who have been in ionizing radiation for 20 years. I know we are all going to have the same difficulty in learning the new language and applying it to new techniques. The other elements of the electromagnetic spectrum are not going to be quite as susceptible to the same techniques, in terms of control, as X-rays and radium. There are some new elements, new problems, and some new twists; and I will let Mr. Duane Solem give you an outline of where we believe and where the industry believes the laser and microwave sources are going and where we are in setting standards.

MR. SOLEM: I am going to try to be very, very brief. The problems as I see them with respect to lasers and microwaves are:

(1) the number of lasers and microwave sources that we have now and are going to have in the future,

(2) the variations in exposure limits,

(3) the occupational exposures from these sources and the potential exposure from the sources which we now have, and

(4) the lack of data on current public exposure.

In general, we know that practically every industrial field is using lasers. About 10 years ago use of the laser was established, and right now it is about a $100 million market. By 1977, it should reach $200 million.

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[2] Formerly, Staff Officer, Division of Electronic Products, Bureau of Radiological Health, Public Health Service.

Eight years from now the greatest gain in laser usage will be made in advanced technology. Of course, research will show some increase, and military usage will increase substantially. All communication facilities have advanced very much in laser usage, as have drilling, metal work, chemistry and physics. The greatest gain will be in advanced technology where there will be an increase of about 60 times. By 1967, there were about 30,000 continuous wave (CW) lasers that were used for surveying and similar applications. About a hundred thousand units per year were sold in 1967 and 1968, and perhaps three hundred thousand units per year now.

As far as I know, there are no exposure limits for the general public. Occupational exposure limits require a little bit of explanation. The exposure limits which exist in industry and in government--I have looked through about 8 or 10 different exposure limits--are rated in different ways. They depend upon whether the exposure is at the retina of the eye, whether it is at the cornea, whether it is a brightly lit room and the pupil is very small, or very large, so that there is no one technique which you can use to compare all the standards. It requires a lot of interpretation and playing around with formulas and numbers.

I have chosen representative means of evaluating exposure limits. One is at the retina, one at the cornea. A number of exposure limits have been set by various agencies or industries. You can see that for retina exposure some people will say, "Well, this is safe," and other people will say, "Well, no, this is safe." The worst discrepancy comes from exposure at the cornea, like we get from a small laser. The lowest tolerance rate exists with the CW laser.

In 1967, a State survey estimated about 30,000 persons were occupationally exposed to laser radiation. Perhaps the number has increased to 90,000 or 120,000 now.

There are four general areas where microwave sources are now being used--in industrial processing, in food vending establishments where prepacked food is heated, in home use of microwave ovens, and other areas.

Within industry, there are probably five or six thousand industrial microwave heaters. There are between 20,000 and 30,000 microwave ovens in food vending establishments.

Now, in terms of home microwave ovens; right now there are about 20,000 home microwave ovens sold per year. If the oven would sell for $350, the sales could double. In 1962, practically none were sold and in 1969, about 40,000 will be sold. The increase will be due in part to microwave ovens imported into this country from Japan. The sales price in Japan is $150 per oven. I don't know what the sales price would be here, but the Japanese ovens could double the present sales rate if they do indeed hit the market. They have already been submitted to the FCC for approval.

There are many thousands of other radar and microwave sources in existence.

In regard to industrial exposure limits, there is about 1,000-fold difference between the United States and Soviet Union values. The current United States limit is 10 milliwatts per square centimeter, while the Soviet Union value is only 0.01 milliwatt per square centimeter.

We have no idea how many persons are exposed to microwave devices. The microwave industry employs about a half million people; how many of these are exposed we don't know. We know in a general way the public is exposed, but we don't know the significant exposure level.

For about $100, that little 15-year old electronics expert in the neighborhood, of whom there seem to be more and more lately, can build a pulsed ruby laser which will fry your eyes to a crisp. Also, for $100, you can put together an S-band source microwave oven, and this can give all of the neighbors' friends cataracts. So for $100 you can do a lot. As I see it, there is a very big problem.

PANEL: IMPLEMENTATION OF PUBLIC LAW 90-602

R. L. Elder, Sc.D., H. L. McMartin, M.D., D. L. Snow,
D. J. Nelson, Jr., R. H. Neill

DR. MILLER: We will now have our panel discussion on implementation and administration of Public Law 90-602. I have asked Dr. Robert Elder[1], Associate Director for the Bureau of Radiological Health, to chair this panel.

DR. ELDER: Today we will review the law and indicate principally how we are trying to implement it.

I hope that those who speak will give you some indication of where we are, or where we think we should be, in implementing the law. I would like to ask Dr. Howard McMartin[2] to start off with Section 360E, which stimulates and sets the course of action we intend to follow.

DR. McMARTIN: I feel like I am speaking to old friends here. Following Mr. Hansen and some of the rest of the people on the program, I feel that most of the things that I was going to say have been said. I would like to call your attention to Section 357(a)(1)(F) of the law which says:

> "the feasibility of authorizing the Secretary to enter into arrangements with individual States or groups of States to define their respective functions and responsibilities for the control of electronic product radiation and other ionizing radiation."

We have a workshop group of which Dr. Kinsman is the chairman for that particular action. I think the thing is that we invite the participation of the States; certainly there has been no question about the fact that States have been mentioned in this bill, about sixteen times.

I think that Section 360E should have been read very, very carefully. Let me take time to read it to you, because I think it is important. It is as follows:

> "The Secretary is authorized (1) to accept from State and local authorities engaged in activities related to health or safety or consumer protection, on a reimbursable basis or otherwise, any assistance in the administration and enforcement of this subpart which he may request and which they may be able and willing to provide and, if so agreed, may pay in advance or otherwise for the reasonable cost of such assistance,

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[1] Presently, Acting Director, Division of Electronic Products, Bureau of Radiological Health, Public Health Service.

[2] Special Assistant for Regional Operations, Environmental Control Administration, CPEHS, Public Health Service.

> and (2) he may, for the purpose of conducting examinations, investigations, and inspections, commission any officer or employee of any such authority as an officer of the Department."

That sets it out pretty clearly as far as we are concerned, and I think it has been repeated several times. I don't think there is any reason why we need to go into it any more. I would like to repeat to you that we have arranged this program to try to establish the type of communications network that we are going to try to keep going from now on, so that each of you will communicate with each other, and that you can communicate with us.

DR. ELDER: I think the area that has attracted paramount interest is the standardization procedures and the overall concept of standards. In terms of our priorities, and what we can do and what we cannot do, Mr. Donald Snow[3] will discuss with you Sections 358 and 360F. This will indicate the implication of performance-type standards in contrast with the use-type standards, which many of our discussions have centered upon this morning.

Section 358

MR. SNOW: Mr. Chairman and members, let me first give you a definition of a performance standard, since for the next few minutes we will center our attention on this subject.

A performance standard is a statement requiring a certain set of conditions to be fulfilled, by stating the results which must be achieved by whatever method is used.

Now, let us start with Section 358(a)(1) of the act which states:

> "The Secretary shall by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from such products if he determines that such standards are necessary for the protection of the public health and safety."

I emphasize the word "if" because I believe there is a process involving determining that a need exists for a standard which has to go on well in advance of the actual standards setting. This is necessary so that the standard may have the proper background to withstand any legal assaults in the future. In continuing, the act states:

> "Such standards may include provisions for the testing of such products and the measurement of their electronic product radiation emissions, may require the attachment

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[3] Director, Office of Criteria and Standards, Bureau of Radiological Health, Public Health Service.

> of warning signs and labels, and may require the provision of instructions for the installation, operation, and use of such products."

Then, it prescribes that:

> "...the Secretary shall consult with Federal and State departments and agencies having related responsibilities or interests and with appropriate professional organizations and interested persons, including representatives of industries and labor organizations which would be affected by such standards..."

The Secretary is charged by the act with giving consideration to the latest available scientific and medical data and those standards which are currently recommended. He must also be able to insure that the standards are reasonable and feasible.

Section 358(a)(2) states that different performance standards may be required for different electronic products in order to recognize their different operating characteristics and uses. I can foresee that there could be a variety of standards, depending upon the particular type of product, and on the variations of that product.

Section 358(a)(3) specifies that the performance standards prescribed under this section shall not apply to any electronic product which is intended solely for export providing that the shipping containers are properly labeled and tagged, and also providing that the product meets all of the applicable requirements of the country to which such product is intended for export.

Section 358(a)(5) provides for exemptions being granted with respect to the provisions of Section 358 where electronic products are intended for use by departments or agencies of the United States.

Section 358(b) pertains to regulation prescribing, amending, or revoking a standard, and mentions that these regulations are subject to the rule-making procedures covered by the Administrative Procedures Act. The provisions of the Administrative Procedures Act govern all regulatory agencies of the United States Government. Some of the procedures in this act pertain, for example, to how proposed standards are published in the Federal Register, and how the replies, received from interested organizations and individuals, are handled.

Section 358(c) calls for regulation prescribing, amending, or revoking a standard to take effect between one and two years after the regulation is issued. The intent of this section is, of course, to provide a changeover period for industries.

Section 358(d), numbers (1) through (6), pertain to available legal recourse under the Public Law. A full record of the proceedings on which a standard is based must be developed and must be on file. Subsections

(1) through (6) provide that any person who will be adversely affected by such regulations, i.e., any individual or organization, may file a petition for relief in the United States Court of Appeals in his district. Should the courts require it, and based on the evidence submitted by the petitioner, the Secretary of Health, Education, and Welfare, may modify or certify his originial regulation. It is at this point that the court has the jurisdiction to review the modified regulation and grant relief where appropriate. This is an uncharted area and I don't suppose that any one of us here can predict what is likely to occur when the first court case comes up. As a matter of fact, the definitive interpretation of the act would rest on the results of a series of court cases which would help reaffirm what was the intent of Congress.

Section 358(e) calls for a certified copy of the transcript of the record and administrative proceedings relating to regulations, which are prescribed by the Secretary, be furnished by the Secretary to any individual on payment of the costs for providing a copy of the record and transcript of the proceedings.

Section 358(f) pertains to the Technical Electronic Product Radiation Safety Standards Committee, and the fact that the Secretary shall consult with this committee before prescribing any standard under this section. It is a committee of 15 members; 5 members are from governmental agencies, 5 are from the affected industries, and 5 are from the general public. Included in the general public group is at least one representative of organized labor. There is another route by which the standards may be proposed. The committee itself may propose these standards to the Secretary. All proceedings of the committee are recorded and are available for public inspection.

Section 358(g) states that the Secretary shall review and evaluate on a continuing basis, testing programs carried out by industry, to assure compliance of the standards prescribed and to safeguard against hazardous radiation.

Section 358(h) specifies that, where there are standards applicable under this section, every product shall be labeled or tagged in a permanent manner, with the certification that the product conforms to all applicable standards.

Section 360

If I may, I would like to go to Section 360F. This section is of particular concern to the States. It says that whenever a standard is prescribed under the provisions of this section, no State or political subdivision of a State shall have any authority to establish or to continue in effect any standard applicable to the same aspect of performance which is not identical to the Federal standard. Perhaps later we will have some questions on this point. State or political subdivisions are not prevented from establishing requirements, with respect to the emission of radiation from electronic products, if the product is procured for its own use, and if the requirements are more restrictive than applicable Federal standards.

DR. ELDER: Jack Nelson[4] is going to talk to us about Sections 356 and 360(a) and (b). In so doing, he will give you an indication on priority and the interest we have in developing a specific product standard. In effect, this will be interpreted later on as to the type of relations that we will have with you. I think that as Jack speaks, you might want to read between his lines to see some of the priorities that we are establishing and some of the concerns that we have. Hopefully, through Dr. Miller and Dr. McMartin, the mechanism will be established.

MR. NELSON: I would like to go over Section 360 first, briefly, to show you what has been done in connection with imports.

Section 360

I would like to summarize for you in short form the requirements of the Secretary of Health, Education, and Welfare. Now, I believe for the most part, these are requirements calling for responsibility in terms of the Federal Government. In all cases here where contractual arrangements can be made, there can be local people acting as agents of the Federal Government under some contract arrangement and they may carry out some of these functions. This is in the compliance and enforcement area, so we have to be concerned about our relationships with the States and their active participation in the program as agents of the Federal Government.

With respect to imports, let's go quickly over the principal items. The Secretary of Health, Education, and Welfare, by delegation to the Commissioner of the Environmental Control Administration, may refuse admission of a product not in compliance or not certified. The act provides for a hearing. The importer may appeal this. The Secretary of the Treasury will provide samples for Health, Education, and Welfare for testing or for examination. If samples are not in compliance, the Department of the Treasury shall destroy the products if not exported within 90 days. There is some leeway in terms of time, which is possible under a separate set of hearings.

Part (b) under Section 360, we think is an important point in terms of our authority under the law. This pertains to the execution of a bond by the owner and allowing the Secretary by regulation to adjust the final determination as to admission. This means that if an importer develops a product, microwave ovens, for example, and they come to this country and the standard is in some way violated, they can enter under the act by the importer posting a bond assuring that he will bring these products in compliance. They then can be sold in the United States if it is the judgment of Health, Education, and Welfare, that these products can be brought in compliance and can be made safe. So, our understanding right now is that for the most part, the import provision applies to products with standards.

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[4] Special Assistant to the Director for Special Projects, Bureau of Radiological Health, Public Health Service. Formerly, Chief, Division of Electronic Products, Bureau of Radiological Health, Public Health Service.

Section 360(c) states that the expenses in connection with subsections (a) and (b) will be borne by the individual or the seller making the device.

Now, Section 360(d) requires the deputization of an agent by a manufacturer offering electronic products for importation. I mention this because electronic products are coming in from European sources and Asian sources. Each manufacturing company has a designated agent. Through this process the Secretary of Health, Education, and Welfare, through the Commissioner of the Environmental Control Administration, deals directly, legally, and officially with this agent. Then we have some point of contact for sources of products from outside the country.

Section 360A. These are the authorities in the act where all the framework of records, inspections, uses are stated. The right of entry was a serious point of discussion between industry and government in developing this legislation. There is the authority which permits entry and inspection for good cause, of any warehouse, factory, or establishment.

The good cause under the law is stated in subitem (a). If the manufacturer is not in compliance once, or had a defect once, then good cause is established for entry for inspection. All of these actions are subject to final court review.

The next subitem (b) requires manufacturers to maintain testing records. As I understand it now, our whole staff is having a real struggle with determining what types of records are needed. We would like to have your suggestions and your experience with respect to record-keeping both in the atomic energy area and other elements of State government, because this can be a burden on both government and industry. We have to have an effective record-keeping system.

Subitem (c) requires the manufacturer to describe his products, particularly with respect to safety, and labeling and instructions on how to operate and how to install in some degree.

Subitem (e) of 360A covers trade secrets. That is, employees of the government have to be careful about proprietary information in investigations for public information or court information. The investigation must be properly conducted.

Finally, subitem (f) permits the Commissioner of the Environmental Control Administration to require dealers and distributors to maintain or provide to the manufacturer the information necessary to identify and locate products applicable to the standards. This goes back to the old recall system of industry; that is, if he had a defect or a noncompliance product, how do you get to the person who has the product and get it back for correction purposes?

In each of these areas we have a great deal of work to do in order to develop regulations and issue instructions to industry that will make the act truly effective in terms of a compliance program. This, in addition to having our standard by 1970, is going to take a great deal of our time.

The next section is 360B, Prohibited Acts. I think we ought to go over what the law says we can and cannot do in terms of prohibited acts.

It shall be unlawful "for any manufacturer to introduce or to deliver for introduction, into commerce, or to import into the United States, any electronic product which does not comply with an applicable standard prescribed pursuant to section 358."

It is unlawful for any person to fail to establish access to records, or to permit entry or inspection, as we stated earlier.

Manufacturers must report on testing for compliance. We have to get information from industry on their test programs. They are to preserve information necessary to identify or locate products. This is what we call certification, and they have to issue a true test. They cannot issue false and misleading information. The manufacturer must notify the customer of any defect or noncompliance with standards, and the manufacturer must replace or refund the cost of the product. The requirement to readily replace or refund the cost of the product, is an effect on industry.

Under Section 360B(b) an exemption may be granted by the Commissioner, Environmental Control Administration, to protect the public health or welfare for the purpose of research, investigation and studies, demonstrations or training, or for reason of national security.

Section 356

Finally, I would like to talk over provisions of Section 356, Electronic Product Radiation Control Program, just reminding you that the delegation under the law has been made down to the Commissioner of the Environmental Control Administration. The Bureau of Radiological Health has the responsibility for a day-to-day operation under the law.

Section 356 spells out what our technical responsibilities are. This is the authority for the complete technical and scientific program which will support Public Law 90-602. This has to do with microwaves, all electronic products, that come under the definition of electronic products under the act, and, of course, this law requires liaison with other Federal and State departments.

I will tell you that the priorities now are at least in terms of operations. Bill Mills has told you something about what biological priorities are, and biological effects. We still have to face up to the X-ray problem. I will have to agree that there is still work to be done, but I think we know how to solve it. Probably the next will be either the laser or microwave area, and frankly, they are two different problems.

I equate the microwave situation today to something like the days of atmospheric testing, where we had a contaminant moving freely in the environment without knowing exactly what the levels were, and not knowing how to control it without preventing the use of that material. Now, perhaps I am a little pessimistic. Perhaps we are not quite as naive in the microwave area as we were in the early days of fallout, but I am not sure.

The laser, if I may make an analogy, is something like in the early days of X-ray machines, where we were using very powerful and dangerous tools, that unless you use them very carefully, they can cause considerable damage. I think the environmental public exposure aspects may far, far exceed those of the X-ray machines. There is no question of involvement of a great many people, and it may extend beyond the professional or specialist use of the device, and have some very serious control problems.

DR. ELDER: Thank you very much, Jack. I liked the phraseology that you used to compare the environmental contamination history in terms of the microwave problem and laser problem. I think Jack has outlined some of the problems that we have in establishing the mechanism by which we are going to implement the law, legal action, contract relations, or what have you, in the implementation of this law. The burden is going to be very heavy upon us to establish the legal format of this relationship. We are going to be dealing with you in a completely new area of radiation. We would appreciate receiving your opinions on priorities. We have ours, and others may have different ones, but I think that looking at it from your point of view, you may want to interject your views, and I am sure that Jack would weigh them carefully.

Mr. Robert Neill[5] will speak on Sections 359 and 360C, and will outline for you what we are trying to do to establish a compliance-type program.

MR. NEILL: In implementing Section 359 of the act, we have established a Compliance Office to address itself primarily to assuring that electronic products will comply with the provisions of the act.

Section 359

Section 359 states if a manufacturer discovers that an electronic product has a defect or does not comply with the applicable standard, he shall immediately notify the Secretary. The manufacturer is then obligated to furnish notification to his customers with reasonable promptness of the existence of this defect or failure to comply with the standards. The manufacturer would then be obligated to replace, repair, or refund these products--and this may entail a substantial cost to him.

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[5] Acting Director, Program Office, Bureau of Radiological Health, Public Health Service. Formerly, Director, Compliance Office, Bureau of Radiological Health, Public Health Service.

The manufacturer can request an exemption from the notification provisions of Section 359 if he feels that the particular defect involved does not constitute a significant risk of injury to any individual. He can then present his case to the Secretary who will review the facts and determine whether or not it is a reasonable request that the hazard does not constitute a significant injury. The Secretary can then grant an exemption from the notification provision. If he does not, the manufacturer must immediately begin correcting the defect.

This can involve substantial amounts of money. We are all familiar with the General Electric case involving 100,000 color television sets which was estimated to cost the company about three million dollars. Manufacturers of color television sets have cooperated with us in whatever way possible in assuring adequate positive control of the program within their companies to assure that another incident of this magnitude doesn't occur. We have been very happy to get this cooperation and assistance, but we recognize that in other instances that may come up involving substantial costs to a company, we must be absolutely correct in our demands or requirements placed upon the manufacturer.

To recapitulate, a manufacturer of electronic products can have trouble and possibly serious financial trouble on two counts. One is failure to comply with an applicable standard. As Mr. Snow indicated before, we are taking steps to develop performance standards for applicable electronic products. Before we can approve a performance standard, it is necessary to indicate that a standard is needed and required. States are in a position to ascertain which are the highest priority problems and whether or not a problem even exists. The Secretary is not empowered to set standards for electric light bulbs without demonstrating, according to the language of the act, that such a standard is a desirable thing and is needed.

The second basis in which Section 359 is involved occurs when the product contains a defect. The 90th Congress did not define precisely what is meant by a defect in this particular act, Public Law 90-602. At first, it struck me as being a real problem and a great difficulty. If they hadn't defined it, how are we going to go about this? As it turns out, I think it is generally in all of our best interests to participate in helping to define exactly what it means. We obviously must be clear to the manufacturer as to what is meant by a defect, because as of now, if the Secretary finds that a defect exists, he is obligated to inform the manufacturer immediately. This isn't six months later, or a year and a half later, it is immediately, it is now, and it is the language of the act. There is nothing punitive involved here. There is no court action involved. The language of the act is straightforward and direct and explicit. It says if the Secretary determines or believes a defect in an electronic product exists, he shall inform the manufacturer immediately. Similarly, the manufacturer is obligated to immediately inform the Secretary if he determines that such a defect exists.

We have to be clear to the manufacturer as to what we mean to regulate under the act. We hope to incorporate your comments, remarks, and advice in these areas prior to publishing implementing regulations in the Federal Register, as required under the law. We are certainly interested and welcome your comments on the definition of "defect" as an item which relates to the safety of use, or poses unnecessary radiation exposure, or is a violation of current good manufacturing techniques, or entails a significant risk of injury to any individual. These are the kinds of observations that we also hope to obtain from you in your comments.

Section 360C

Section 360C describes the penalties associated with violations of the act. No criminal procedures are involved. These are civil penalties, with a maximum penalty of $1,000 per violation and $300,000 for a series of violations.

In the general area of voluntary compliance, I would like to think of it in a similar context as one of our sister agencies, the Food and Drug Administration. They tend to think of voluntary compliance as a part of their training programs. These include training courses such as the type we have conducted over the years, one- or two-week courses available to State health department people, representatives of industry, and other concerned participants. We are extremely interested in knowing the kinds of courses that you feel are desirable and necessary in these new areas. Perhaps we can get Dr. Kinsman to write a new handbook for non-ionizing radiological health. The kind of courses which are needed include theoretical physics, laser measurements, practical measurements in the field, etc. We have the opportunity at this session to get your considered views and opinions.

I think Mr. Snow mentioned Radiological Health Data and Reports, a publication I helped start in 1960. If there are certain kinds of articles and reports and data that you find would be of greater benefit to you in your own activities, you have the opportunity to make known the specific and different kinds of data that you prefer to see presented in it.

I think we did a very good job over the years in the area of environmental surveillance. The combined national expertise of State and the Federal Government participation in environmental surveillance networks has represented some of the finest examples in joint Federal-State cooperation. I have always urged others in the Department of Health, Education, and Welfare, to emulate these efforts in air pollution and pesticides. We have gotten the radiological data out publicly and we have made this information available to those that are concerned--the scientific community, the general public and Congress. I think it has been a strong influence in answering questions and allaying needless fears.

With respect to the development of standards, a 15-member committee is being appointed to review and evaluate proposed radiation performance standards and submit recommendations to the Secretary. Five members are being selected from governmental agencies including State and Federal

Governments, five members will be selected from the affected industries, and five members will be selected from the general public.

I think it is quite clear at this point of time that the considerable public interest in the area of consumer protection is one that is with us and one on which the new administration is going to push and be pushed. The new administration has made it quite clear that they recognize the importance and significance of this area, and this is going to receive a very high priority within our organization.

DR. ELDER: I would like to close this particular session with a review of Section 357, Special Studies, and on 360D, Annual Report.

The requirement of a report and the responsibility of a report is an indication of the interest and involvement of Congress in the administration of the law. We have seen this in other areas, and probably, our law is an excellent example of the new involvement by Congress in the implementation and execution of a law.

Section 357

In reading through Section 357, you will find specific studies that are required to be submitted by January 1, 1970. All of you realize that you cannot write on a report up to January 1, 1970, and get it in. It is our responsibility to get it done and we are looking forward to having the report completed in draft form by September 1, 1969.

We are actively engaged in several areas. Some of you in certain States have already agreed to help us in the preparation of these reports. Mr. Villforth mentioned the magnitude of the problems associated with radium, and in the Congressional testimony, you will find it was repeatedly pointed out that there is a void in the law in this area.

One of the studies that we are doing, which overlaps several areas and I think will be of great value to you in the States, is on the compatibility and uniformity of State regulations. We are, in this area, comparing your State regulations as published, and going through on a point-by-point analysis basis to compare your laws and regulations with the model code. This is something that we have wanted to do for a long time, but we essentially could not give it the priority until this study came along.

One of the studies on the need for standards for the use of nonmedical electronic products is a sleeper. It was put in deliberately because the major users of electronic products are the technicians. Initially, the word "medical" was used in one of the drafts, but it was deleted, and the word "nonmedical" was inserted. Essentially we are required to study a minority group of users of electronic products. We are looking mainly at types of accelerator users, and would like to get some information on microwave operators.

You will note the State Program Directors' meeting we are having today is responsive to this section of the law. Not only are we required to study and make a report, but we have to, if you read the last Section 357, report all dissenting views. Although we may come out with recommendations on these studies, your health officers will have the opportunity to review the recommendations and thoughts of this group. These will be used with the minority opinion attached to them.

We have a study on used X-ray equipment. I think this one is significant, because this is the first time we are getting back to the problems that you are wrestling with on a day-by-day basis. For example, how much and what is the volume of sales of used X-ray equipment? If I remember the figures correctly, back about 10 years ago it was indicated that 25 percent of X-ray machines purchased were used machines. Obviously, in this type of a market a standard-making organization won't be effective. The main question we are essentially asking ourselves is, "What can we do to upgrade those?"

We are also attempting to use the X-ray survey physical data that you have been supplying. I think I can promise you that by January 1, 1970, this data will be available for your use. We also have a division study that some of you know of. This is the high school electronic products study. It is not a statistical study, but it is essentially a small study to get some indication of the types, and the problems associated with the high school electronic products. In some cases we have found that a medical diagnostic unit was being used. Some of the smaller units can also have a very high radiation emission.

What we might conclude from Section 357, noting that Congress was concerned when they passed the final law, is that we do not have the authority to cover some of the real critical problems.

Obviously, the information we are asking you to supply will be reported to Congress. It will also be the basis for which we can tell Congress what kind of programs are needed in your State and in the Federal government. This is a real opportunity for us to essentially put the status of some of the problems in this country into perspective.

Section 360D

Now, one section I wanted to go into briefly is the annual report. Anyone who looks at that would hold up his hands and scream and walk away, for we are required on a yearly basis to cover the biological effects, including the statistical effect of injury from electromagnetic radiation upon the population.

As you will recall, the United Nations has made a six-year study at a cost of $6,000,000 and at the end of that time they concluded that ionizing radiation was just too big a problem for them to study completely. They were only studying ionizing radiation, yet they suggested that this energy range had to be broken down into smaller portions if one was to effectively handle it. Under this law, we are required to take the whole step and report it on a yearly basis.

If you will please turn to that section you will find it has some very interesting legislative history. You will see that we are going to be required to state on a yearly basis what standards we have established, what are our problems, what is our level of activity. Particularly note that last little section which says that on an annual basis we may recommend legislation to promote the cooperation of effort between States.

I hope you will look in perspective at the overall program that we have going today, and I would like to have your comments on the needs we have if we are to obtain your participation. In Section 360D(b) you will note "...to promote cooperation among the several States..." The power given to the Secretary to recommend legislation to Congress is a very powerful tool. We just can't go enacting legislation without some authority. There is a high protocol involved, but this essentially establishes a relationship between the Department of Health, Education, and Welfare and Congress, to tell us what the problems are in radiation today. We did not have this a year ago. The annual report puts a tremendous load on our agency. We have an opportunity, on a yearly basis, to update the literature, to update the problem, to focus the type of attention on the very philosophy that you are living under and why we are here today. Congress has opened the door for us to tell them what our problems are and what the future needs to be, and they closed that session by making sure that you State people were included.

I think one of the interesting things about the law that wasn't brought out is the concept that the Secretary may, after a Federal court might fine an industry, reduce the fine.

Discussion (entire group)

MR. FRANKEL: In Section 360F, Effect on State Standards, the word "identical" is used. My question to you is, "May a State have performance standards more rigid than the performance standards promulgated by the Bureau of Radiological Health?"

DR. ELDER: The whole concept here is identical. To the best of our knowledge, and until it is tested, there is no way of knowing. For this reason we are now faced with every standard promulgated by States. We don't visualize any problem in the standards used by the various States, and I think we can solve it before it comes up.

MR. LITTLE: Relative to this same question, if a State standard applies only to electronic products which are used within the State, and not in interstate commerce, could not the standards be different?

DR. ELDER: Well, I think that really is going a little beyond the point we are talking about. It is pretty difficult to visualize any product, or any product that could be made of components, to which the law would not be applicable.

MR. SNOW: I don't have the answer, but the only provision, as you have heard earlier, of the law is that if the product is used by any State, and not within the State. I think a lot of these things are going to have to go through legal review, court tests, and hearings to ever be able to answer your question specifically.

MR. WUKASCH: I am sure Marshall will recall in Washington at the conclusion of our last Agreement State meeting, we went over to Health, Education, and Welfare, to get a briefing on this law from a representative of the Library of Congress who was a legislative consultant. He commented that shortly before the law was passed, an amendment in regard to licensing X-ray technicians was withdrawn before final passage upon promise that the American College of Radiology this year would introduce some legislation in regard to licensing X-ray technicians. Is anyone present here today who knows anything about the status of that?

DR. COLE: The participation of the American College of Radiology in licensing of radiologic technologists came up at a meeting in Atlanta about a month ago. As you know, two years ago we worked with the College and with the American Society of Radiologic Technologists in developing a model legislation for State licensing of X-ray technologists. The College has decided to come back into this program again, and will, I hope on April 17, 1969, meet with the Bureau and with representatives of the American Society of Radiologic Technologists in trying to draw up model legislation for the States. Somebody asked about a State representative participating in this meeting. I was so flabbergasted in Atlanta to find that the American College, of which I am a member, wanted to again participate in this, and also Leslie Wilson[6] said that he would like to again participate, that I have not gotten my thoughts together on this. I will certainly let you know when the conference will be held and will request a State representative.

MR. GERUSKY: I would like to make the appeal that States be consulted whenever any model legislation is prepared. We are constantly being told that our regulations do not match the regulations of the Council of State Governments, yet we have had no input in it at all. We are the people who have been working with regulations for some 20 years, and we have yet to participate completely, or even partially, in the formulation of new regulations, no matter where or what they are for. I would like to say that we, as a Conference of Radiation Control Program Directors, are ready and willing to participate, and request your help in getting us to participate in this type of endeavor.

DR. ELDER: I think relative to the X-ray technicians, I will refer you to the Congressional hearings. The official policy on the part of the Department essentially remains the same, pending further legislation. We will work with the States in developing model programs and assisting them. I guess we can interpret that we have a strict order to do this. I don't see any reason why we can't. I think Dr. Cole will follow through on this for he is handling all contacts made by the Bureau on

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[6] Member, Board of Directors, American Society of Radiologic Technologists.

X-ray techniques and model legislation for us. If anyone has any recommendations or suggestions on how we can get your comments, I would like you to specifically write to Dr. Cole to implement your request.

MR. WILMS: To what extent will these performance standards enter into the installation of a device? Here, I think we are getting into an area of use versus performance standards. A number of us are interested, for instance, in the installation of X-ray machines, and I would like to know what extent this bill will have.

MR. NELSON: I think this again is a matter of specific standards and how to draw up the standards, and how we test it, both through the hearing process and the review process. I know from hearing testimony from the record that is built in Congress, that it was the intent of Congress that these standards be related to safety of use, that as far as the word performance would permit, standards would go to the facilities, to the equipment, to the gadgets, and would specifically spell out in the law the requirements for technique of measurement. I think the only answer to your question is that we try a few of these standards, both through the advisory committee and through experience in the State and the field. We may have to interpret the meaning of the word "performance" that is required for producing the right type of standards which gives you the right type of protection. I think it is not a simple answer, yes or no, whether we will include facilities or equipment. It will have to be on a case-to-case basis.

MR. GERUSKY: I might close this session by mentioning the headlines in the morning paper which said that problems give you opportunity. It is true that we have problems in this law, but we also have a great opportunity.

The first thing on the agenda tomorrow is for each workshop chairman to report on his workshop. After each report, there will be liberal time for discussion from the floor. The following day we will have the final reports of the individual workshops. The first workshop to report will be Compatibility, Dr. Roy Parker, Chairman.

Workshop No. 1

COMPATIBILITY[1]

Roy A. Parker, Ph.D.[2]

The Compatibility Workshop did not try to define compatibility. I think you recognize that this is a nearly impossible problem. We did undertake to define a problem area, "incompatibility." This can be summarized as follows:

Sources of radiation manufactured in one State and distributed in another. These sources of radiation are not only radioactive materials, or X-rays, but microwaves and lasers.

There is a particular problem with the uniform treatment of users between the various States. The problem arises from the acceptance of the home State's evaluation of users. For instance, if you have a licensee that is operating temporarily in my State, I would like to know in general how you feel about that licensee's operation. We think there is a problem in the exchange of information, program inspection from one State to another.

There is a problem of Federal jurisdiction within the States. We think some of the Federal representatives are not absolutely recognizing the responsibility of the State level. Of course, it is probably our fault that you don't know what we can do down at the State level. We think there needs to be more cooperative radiological health efforts across the board. We know, for example, that there is variation in the radiological health practices in Veterans Administration hospitals as opposed to Public Health Service hospitals.

We know there are problems in areas such as shipments of radiological materials between States, where there would be agreement-type material or non-agreement-type material. This is an area of protective Federal jurisdiction where the States are not directly involved, as undoubtedly they should be.

There is a problem in the enactment of the Federal standards regulations; namely, that again there is no recognition of State responsibility within this area. We feel that when you take a final draft or even a draft, there is a unilateral enactment. We have no input as to what is going into it in the first place and many of us do not like it. We recognize that there is a variation of radiation control programs between the States and within the States. We know there is a large variation between State A and State B on a number of items which they do. There is a problem of the reciprocity of radiation personnel; not sources of radiation, but radiation personnel, like industrial radiologists, X-ray technicians, oil well loggers, medical technologists, and qualified experts, whatever this means. These are about the seven areas that we wanted to confine ourselves to in the Compatibility Committee.

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[1] See Appendix A for membership of the workshop.

[2] Director, Division of Radiation Control, Louisiana Board of Nuclear Energy.

We tried to identify the reasons for this problem and why there is a problem. Radiation machines manufactured in one State and then shipped to another confuse the compatibility problem. There is a lack of uniformity in evaluating sources of radiation between the States. This we recognize as not being too great a problem in the agreement materials area, but we certainly have a tremendous problem with radium devices. There is not the proper dissemination of information.

The problem involves uniform treatment of users between the States. There is no routine means for the exchange of information. For example, although I cannot give you my special report for Louisiana on radiographer XYZ, I can give you an evaluation, a summary-type evaluation of his operations. There is a lack of acceptance by some States of other States' evaluations. We have got to be a little bit less defensive about our own philosophy and we have got to trust you, our Federal radiation control people, in these joint sessions. This conference can do a lot for uniformity.

Federal standards of regulation--here, again, there is a lack of communications. There is no liaison directly between the States and the Federal agencies. Radiation control programs vary between and within the States.

What can we do about this? What are some of the possible solutions in consideration? We can certainly develop minimal basic evaluation procedures and criteria for the sources of radiation manufactured in one State and distributed in another. We can disseminate this information more routinely through some vehicle such as the Bureau of Radiological Health. We can also set up some basic criteria in the evaluation mechanism for, shall we say, a presentation of the various State programs. We are going to underscore this as being one of the most important aspects that comes out of this proceeding, that is, accreditation, a uniform treatment of users between the States. Here we can develop criteria for inspection. We have to develop a procedure for exchange of information. We at the State level have to establish direct liaison with our Federal agencies. We have to encourage the Federal agencies to communicate among themselves. I think there is a problem with one Federal agency that has radiological health problems, communicating with another Federal agency with radiological health policy and capability. I think the problem of the radiological health program director is to try to take a more active role in the review and enactment of Federal legislation. I think we have to establish some mechanism for letting a competent program director speak for us on at least 90 to 95 percent of these matters.

We are going to recommend the formation in one form or another of seven committees.

The Compatibility Workshop hereby recommends the establishment of the following committees:

1. Accreditation Committee: An Accreditation Committee to evaluate and determine radiation control program compatibility, adequacy and quality. This can be utilized to determine eligibility for Federal funding under Public Law 90-602 and other Federal assistance programs. This can assist in determining compatibility with other Federally sponsored programs. This activity will serve to improve the general quality of radiation control programs and it will function as an administrative quality control mechanism. The committee should be composed of representatives of the Conference of Radiation Control Program directors, an Atomic Energy Commission representative, and a Bureau of Radiological Health representative.

I would like to discuss this for just a few minutes. This is not another one of these things where we are advocating some people visiting more States more often, or something like that. We view this as a mechanism that we on a State program level, and the people on the Federal program level are helping us in the State strengthen our program. We realize that everybody is trying, but in some areas resources are limited, so we need an effective voice; this can be the Accreditation Committee, to help you (in the State) improve and upgrade radiation control programs.

2. Federal Liaison Committee: This committee will prepare a statement which describes State and local radiation control program capabilities. It will be the duty of this committee to establish and maintain liaison with Federal agencies in areas of mutual interest and concern. The committee shall also serve as a focal point to direct attention of the Bureau of Radiological Health to specific problems of radiological health compatibility which may occur from time to time between the State and Federal agencies.

3. The State Public Law 90-602 Utilization Committee: An ad hoc committee of radiation control program directors to advise the Environmental Control Administration on the methodology for the utilization of State programs in the implementation of Public Law 90-602.

This is the committee that was asked for, that we already had under consideration, and that we think is an excellent way to help design and mediate the State role of Public Law 90-602.

4. Standards, Regulations, and Legislation Committee: A committee to represent the Conference of Radiation Control Program Directors in the development of both Federal and State radiological health standards, regulations, and legislation. This committee shall comment for the Conference of Radiation Control Program Directors on all such matters and the committee shall also inform the individual program

directors of proposed standards, regulations, and legislation which are under consideration. This committee shall establish mechanisms for obtaining standards, regulations, and legislation proposed by the Atomic Energy Commission, the Bureau of Radiological Health, and other Federal agencies at the earliest time possible and shall attempt to play a role in the drafting of these documents.

5. Industrial Relations Committee: A committee for the purpose of serving as a focal point for industry involved in interstate compatibility problems.

We have all heard the manufacturers state some of their problems to such people as the Atomic Industrial Forum. I think this was called to the specific attention of some of the Agreement States about two years ago, where the industry didn't even realize that we in Agreement States had such mechanism to do these things, whereby we recognized the uniformity existing within our States. So we really need a vehicle by which industry can focus some of their problems to the State Program Director.

6. Priorities Committee: A committee to advise the Bureau of Radiological Health, the Atomic Energy Commission, and the other appropriate Federal agencies on the establishment of priority needs in radiological health and radiation control problems. For example, there are immediate needs for a sealed source device catalogue for radium and other nonagreement sources of radiation, a descriptive catalogue of industrial X-ray radiography training courses, and the establishment of radiological health manpower requirements.

7. Interstate Relations Committee: A committee for the purpose of developing methodology for exchange of information between regulatory agencies on user activities. This may include procedures for exchange of inspection reports and user operations in a given State. The committee shall also determine basic requirements for interstate reciprocity for radiation personnel including X-ray technicians, industrial radiographers, oil well loggers, medical technologists, qualified experts, and other users.

These are the committees which we think necessary in increasing the individual roles of the State, the Federal Government, the persons in radiological health, radiation control, etc. In addition, we have three resolutions which we are advocating.

Resolutions

The committee recommends that the conference adopt the following resolutions:

1. States shall use model guides for enabling acts and regulations to ensure uniformity and compatibility of radiation control programs between the States.

2. State radiation control programs should be vested with primary jurisdiction over the control of environmental radiation.

3. The Conference of Radiation Control Program Directors should be supported by the United States Public Health Service, the Atomic Energy Commission, and other appropriate Federal agencies in the interest of radiation control compatibility and the cooperative implementation of Public Law 90-602.

Discussion (entire group)

MR. SNOW: I would urge that the second resolution, which concerns State radiation control programs, with primary responsibility over the control of environmental radiation, be held in abeyance pending the other workshop reports. I believe these reports may address themselves to other issues which must be considered in their entirety before this resolution can be considered.

MR. HARRIS: I think that in the last resolution, the support should not be limited to Public Law 90-602. There are other Federal laws pertaining to radiation control that you may want to also include.

DR. R. PARKER: The last resolution is not specifically directed to Public Law 90-602. It means only that the total money you are asking for is funds in support. We like money like anybody else and I don't know at this present time where we are going to get it, but we think that the main point here is that the Conference, our organization, has got to be continued and supported, in the interest of radiation control compatibility across the board, not necessarily Public Law 90-602. We emphasize at this present time that the cooperative implementation of Public Law 90-602 will be a direct result of this funding. This was put in for emphasis, and not to specify that this is the only place where it should be used.

MR. GERUSKY: This is the most compatible group I have seen in a long time. Thank you. We have possible overlapping recommendations and resolutions. I think we have to go through these reports before we really vote for, or agree to any one particular resolution, so I would suggest that we should have a full discussion of each of them today, but hold off on any final decision until tomorrow. The report from Workshop No. 2 will be given by Dr. Kinsman.

Workshop No. 2

STATE-FEDERAL ROLE IN RADIATION CONTROL[1]

Simon Kinsman, Ph.D.[2]

Radiation Control Nationally

There is a need for control of radiation at all levels of government. This need can be satisfied by the control jurisdiction residing in a minimum number of (1) Federal agencies and (2) State agencies. Since one Federal agency, the Atomic Energy Commission, has been delegated the authority to control and regulate one component of the radiation--namely that from source, by-product, and special nuclear materials--and since this type of radiation is classed as ionizing radiation, it is desirable to consider the national control of radiation under two subdivisions: (1) ionizing and (2) non-ionizing radiation. For maximum control by a minimal number of jurisdictional groups, the reports will consider control for each of these radiation classifications: (1) Federal agency(s), (2) the State, and if necessary, the joint responsibilities in specific cases with continual recognition for compatibility in regulations, standards, and implementations.

Ionizing Radiation--Federal Control

The Atomic Energy Commission regulates all source, by-product, and special nuclear materials except those materials regulated by States pursuant to an agreement between individual States and the Atomic Energy Commission. State agencies regulate other sources of ionizing radiation in areas under their jurisdiction. The Atomic Energy Commission regulates materials subject to its jurisdiction which are used in Federal installations. To avoid a gap in the control of other sources of radiation in Federal installations, it is recommended that the Department of Health, Education, and Welfare, assume regulatory authority over all sources of ionizing radiation not regulated by the Atomic Energy Commission. This authority could be delegated to the States.

The Atomic Energy Commission has a program of consultation, training assistance, and exchange of information to (1) assist States preparing for an agreement and (2) assure continuing compatibility and higher quality of the regulatory program of the Atomic Energy Commission and Agreement States.

With respect to radiation sources other than source, by-product, and special nuclear materials, the Department of Health, Education, and Welfare, formulates national policy, does national planning, carries out research and provides training programs for radiological health personnel--both professional and technical. Technical assistance is provided States in developing their programs. Grants are made to share administrative costs of State and local programs and personnel and equipment are loaned to States too small or limited in resources to undertake a comprehensive program of their own. The Department of Health, Education, and Welfare, through the Environmental Control Administration, the Bureau of Radiological Health, and regional offices, encourages and assists States in assuming responsibilities for control of ionizing radiation. The Department of Health, Education, and Welfare, coordinates national activities in the broad fields of radiological health, especially monitoring of environmental exposure. The registering, licensing, inspection, and countermeasures are considered responsibilities of the States.

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[1] See Appendix A for membership of the workshop.

[2] Chief, Bureau of Radiological Health, State Department of Health, Berkeley, California.

It is recommended that the Atomic Energy Commission and the Department of Health, Education, and Welfare, continue to provide this valuable assistance to the States.

Ionizing Radiation--State Control

Registration, licensing, inspection, countermeasures, and compliance with regulations or conditions of registration and licensing of all sources not exclusively controlled by the Atomic Energy Commission are the responsibility of the respective States. If any State does not have the resources to execute its responsibilities, it may request assistance from the Atomic Energy Commission and/or the Department of Health, Education, and Welfare. In order to insure that all citizens of this country will be provided with similar and effective radiation protection, the requested assistance will be guaranteed and, consequently, furnished until the State can assume its responsibility in controlling ionizing radiation in that State.

States have a special role in the responsibility for uncontrolled radiation sources in the environment as an unexpected result of a Plowshare Project.

Non-ionizing Radiation--Federal

Public Law 90-602 has given the Department of Health, Education, and Welfare, the authority and jurisdiction for control of all sources of non-ionizing radiation in Federal installations or installations under Federal jurisdiction. There is an Environmental Control Administration in the health component of the Department of Health, Education, and Welfare, which formulates national policy on non-ionizing radiation and implements its responsibilities by retaining the right to:

1. Issue and approve regulations under the act;

2. Promulgate performance standards for electronic products under Section 358 of the act;

3. Amend or revoke by regulation under Section 358(a)(4) any performance standard prescribed under Section 358;

4. Exempt any electronic product intended for use by Federal departments or agencies from provisions of Section 358;

5. Establish and appoint members of the Technical Electronic Product Radiation Safety Standards Committee required by the act;

6. Exempt manufacturers from complying with, or direct them to comply with, the act's requirements for purchaser and distributor notification when an electronic product has been found to be defective and for repairing or replacing the product;

7. Exempt electronic products from import restrictions to the extent permitted under Section 360(b);

8. Remit or mitigate any civil penalty imposed for violation of the act.

There is, in the Environmental Control Administration, a Bureau of Radiological Health which:

1. Promotes and conducts training programs;

2. Furnishes technical assistance to States in developing their programs;

3. Specifically allocates funds to States in addition to those available through comprehensive health services (for the execution of Public Law 90-602);

4. Regulates the design, manufacture, import, and export of equipment capable of generating electronic product radiation (EPR);

5. Establishes standards for all electronic product radiation equipment manufactured in the United States;

6. Enforces compliance in Federal installations with appropriate provision for mutual State participation;

7. Conducts, encourages, supports, and allocates specific funds for research;

8. Encourages self-control by industry;

9. Enhances liaison among industry and States;

10. Collates, analyzes, and interprets electronic product radiation emission and exposure data;

11. Promotes liaison internationally;

12. Establishes, improves, and continuously reviews liaison with national organizations;

13. Promotes, establishes, and conducts educational and training activities throughout the United States in such manner that these activities will be readily available to States.

Non-ionizing Electronic Product Radiation--States

It is the responsibility of the States to control electronic product radiation in all areas and activities not preempted by the Department of Health, Education, and Welfare. Some of the functions which will be necessary to execute this responsibility are:

1. Planning
2. Determine needs
3. Resources available
    a. money
    b. manpower
    c. facilities and equipment
4. Goals and priorities
5. Administrative organization
    a. policy formation
    b. coordination
6. Request assistance of the Bureau of Radiological Health through the regional office for any assistance needed to carry out State responsibilities.

Radiation--Joint Roles or Responsibilities

1. Planning
2. Determine needs
3. Establishing and implementing and allocating the resources, available money, manpower, facilities, and equipment
4. Goals and priorities
5. Establish identical authority laws
6. Establish and enforce standards
7. Uniformity in services such as

        a. surveys

        b. reducing exposures

        c. promoting health and healthy environment

        d. emergencies

8. Recruitment and training

9. Research

10. Uniformity in records and report systems

11. Evaluation of results

12. Cooperation with other agencies

Plan of Action

1. The Department of Health, Education, and Welfare, should take appropriate steps to assume responsibility for regulating all sources of radiation in Federal installations presently not subject to regulation by the Atomic Energy Commission.

2. The Bureau of Radiological Health should work as closely as possible with all the States to:

a. Determine their needs

b. Prepare the most important Department of Health, Education, and Welfare Report to Congress January 1, 1970

3. The Department of Health, Education, and Welfare, in consultation with States, should establish a system of priorities for protection of health from non-ionizing radiation hazards.

Special Recommendations

1. That this Conference commend the National Health Physics Society for its immediate action in broadening its purpose to promote control of all electronic product radiation included in Public Law 90-602 except mechanical vibrations.

2. That the Conference of Radiation Control Program Directors petition the National Council on Radiation Protection and Measurements to include recommendations for control of the uses of non-ionizing radiation in its purview.

Discussion (entire group)

MR. ANDERSON: Those of you who have read the law will recognize that the source of our authority is limited to performance standards for electronic products relative to radiation emissions. One thing I might explain to you--this legislation includes no regulatory authority with regard to the use of devices. I think the States think of looking at the "use" regulation side of the picture. In view of this lack of a "use" regulation authority, there is a very large State job here, aside from what they may do in assisting us in enforcing the performance standards related to manufacturing. That was the only point I wanted to make.

DR. INGRAHAM: I need a little more information. I am concerned with Dr. Kinsman's remarks about the intent of what is going on here. Dr. Kinsman indicated that the Atomic Energy Commission has some kind of control over all programs involving all radioactive materials. My understanding is that this is not so, and so my main concern is, "What is the intent of these workshops?" Are we later on, after all of these reports and discussions, going to be asked to approve at a meeting of the whole, all of the detailed recommendations of the various subcommittees, or are we to stand behind only those committee reports we have been concerned with? If we as a group are expected to give unanimous approval of the phraseology of every portion of this report, the section just read by Dr. Kinsman may need some alteration. While it may be compatible with what the Agreement States go along with, it is not necessarily compatible with the understanding of all the non-Agreement States. For this reason, I think I need to have clarification on this particular point: What kind of meeting report is coming out with what sort of authority from the representatives of the several State agencies who have voted "unanimously" in favor of all recommendations?

DR. MILLER: We knew we were going to have a problem with these 10 work areas. In the preplanning of this conference we got together with a select number of State people and identified problem areas; these resulted in the 10 workshops. Ideally, we should all be working on the same problem area, so we could have an agreement. However, since this was the first time we were to be together as a group it was decided to try to do something on all 10 areas , then report back to the entire conference, as we are doing here this morning, and to change these recommendations based on the discussions in a final report by Mr. Gerusky tomorrow morning.

I don't expect you as a group to vote or agree to these recommendations until you have a chance to study them in depth. The support we are seeking is from two areas: the Conference of Radiation Control Program Directors and the State health officers. They will be asked to comment and give their concurrence or objection to certain aspects of the recommendations of this conference. This will be duly noted, and I believe is the only way we can work it. Does that answer your question, Sam?

DR. INGRAHAM: I guess it does, as well as it could be answered.

MR. ANDERSON: One point that has not been discussed at all so far is the matter of qualification of the users of radiation sources. During the process of enacting Public Law 90-602 this was proposed as an amendment but was not included.

DR. MILLER: We are really as concerned as you are about that. I think there is time for one more report this morning. The next report is Criteria and/or Indices, Program Evaluation and Measures of Progress, Mr. William T. Willis.

Workshop No. 3

CRITERIA AND/OR INDICES, PROGRAM EVALUATION AND MEASURES OF PROGRESS[1]

William T. Willis[2]

The charge of Workshop No. 3 was to develop criteria and/or indices for program evaluation and to develop measures by which progress could be measured in the evaluation of programs. This stems basically from Section 357, Public Law 90-602, which empowers the Secretary to make a study of the State and Federal control of health hazards from electronic products, and then it gets down to Section (B), any gaps and inconsistencies in the present control, and in Section (E), measures to strengthen radiological health programs of State governments. So our job basically is to determine how the Federal government is going to come around and evaluate our State programs, and this is not a one-way street.

This evaluation can be on a State level as well as on a Federal level, and we are trying definitely to achieve some degree of uniformity in our radiological health programs throughout the country.

I will not attempt to go into detail on the areas which we considered. I will briefly summarize some of these areas and point out or indicate areas where we had the gravest concern among ourselves as to what these problem areas were.

Due to time limitations the following criteria are not considered by the workshop as a final and exhaustive document. We believe, however, they are a good beginning toward producing a document which can be used in evaluating State radiological health programs.

ADMINISTRATION

I. LEGISLATION AND REGULATIONS

A. Legislation

1. The State should have enabling legislation essentially in conformity with the Council of State Governments' suggested legislation, including authority to enter into interstate and Federal-State arrangements for the control of radiation hazards.

2. Legislation should include authority for licensing and/or registration and inspection of radioactive materials not included under the Atomic Energy Act of 1954 as amended.

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[1] See Appendix A for membership of the workshop.

[2] Director, Division of Radiological Health, Alabama Department of Public Health.

Legislation should also contain the following provisions:

1. Reciprocity between the various States.
2. Coverage of all types of radiation as defined in Public Law 90-602.

B. Regulations

The State should have regulations or other regulatory authority which are essentially compatible with the Council of State Governments' suggested regulations and cover all types of radiation as defined by Public Law 90-602.

(Comment by Mr. Willis: I note that radioactive materials does not specify anything. That is as broad a term as we could think of, and we indicated that legislation should contain provisions for reciprocity and coverage of all types of radiation as defined in Public Law 90-602. Most of our States have got to enact additional legal provisions.

As for the regulations themselves, the regulations again are essentially compatible with those of the Council of State Governments. The reason for adopting this was to achieve some degree of uniformity in radiation control programs throughout the country, and the Council of State Governments is simply the most available model legislation that we have.)

II. FISCAL SUPPORT

The State should have adequate fiscal support to conduct a comprehensive radiation program covering all types of radiation as defined by Public Law 90-602.

Note: The total State budget required to conduct a comprehensive State radiological health program may be estimated by the following formula:

$$\frac{\text{(FY 69 Budget for Radiological Health)} \times \text{Total Man-equivalent}}{\text{(FY 68 Total Man-equivalent)}}$$

$$\underline{\text{Needed for program} + \text{(10\% FY 69 Budget)}} = \text{Total recommended budget.}$$

III. PERSONNEL

A. Radiation Control Program Director Qualifications

The director should have wide experience in public health programming and at least a bachelor's degree.

B. Merit System Classification

The State should have specifications for professional employees functioning in the radiation control field.

C. Job Descriptions

Each State professional employee in the State radiation control programs should have an accurate, up-to-date description of his position, detailing specific responsibilities and authority.

IV. TRAINING

The State radiation control program should have a planned, continuing training program to keep personnel abreast of current developments in the control of radiation hazards.

(Comments by Mr. Willis: I don't see how any radiation control program can be effective if there is a man on the staff who never attends a training course, never goes to a meeting such as this, or any technical meetings at all. How is this man going to be aware of what is developing? Things are moving too fast. We must have adequate facilities and the freedom to continue personnel training.)

V. RECORDS

The State should have a records and statistical system which includes the following components:

1. A continuing integrated registration and/or licensing program covering all radiation sources.
2. Physical survey forms for recording basic data and information.
3. Data accurately and rapidly retrievable.
4. Radiation control program employee "personnel monitoring" results.
5. Fiscal and other administrative records.
6. Records of machine transfers and vendor notification.
7. Records of incidents and investigations.

(Comment by Mr. Willis: As far as records are concerned, the States certainly will have to have an accurate record-keeping system, including many things, such as integrated registration and/or licensing programs covering all radiation sources; survey forms for recording basic data and information.

Radiation control program employee personnel monitoring--here again, we didn't get into this with the idea of the State keeping all personnel monitoring results. We discussed this and we ducked it. Fiscal and other administrative records, records of machine transfers and vendor notifications, and details of this type were discussed.)

VI. PROGRAM ORGANIZATION

A. Responsibility for cognizance, evaluation, and recommendations regarding all State radiation control programs should have a single focus within the State.

B. The program should have an active technical advisory committee that advises on all facets of the State radiation control program.

(Comment by Mr. Willis: On program organization we got involved in somewhat of a conflict with the recommendations of Workshop No. 1. We initially came up with the statement that ideally, all radiation control activities should be located in the same agency. We had such a fight on this with so many words--we came up with one that is a little more simple. I think it still needs to be thought over quite a bit, and this is, "the cognizance, evaluation, and recommendations regarding all State radiation control programs should have a single focus within each State.")

VII. PROGRAM PLANNING AND EVALUATION

Each State should have a written plan of action describing present and future program activities. The plan should include the following basic components:

1. Problem

   In defining the problem, the State should include the extent, nature of the radiation exposures involved, and, insofar as possible, the population affected.

2. Objectives

   The State plan should set forth both long- and short-term objectives based on current and anticipated resources, and target dates should be established for priority projects.

3. Methodology

   The State plan should describe those activities directed to fulfill stated objectives.

4. Evaluation

   The plan should include a method of evaluating (involving the establishment of criteria) the progress of the State program. Important components of the State evaluation program should include an assessment of the radiation hazards and population affected for setting priorities.

VIII. PUBLIC INFORMATION AND EDUCATION

A. The State should have a radiation information-education program and mechanism including the dissemination of information pertaining to emissions from electronic products, and emergency situations.

B. The State should maintain liaison with professional groups leading to seminars, training courses, and public documents on radiation control.

(Comment by Mr. Willis: We suggest that each program try to make the public aware of the problem. At least make the public aware of the many activities of the State program. We feel that in many cases the apprehension on the part of the public is due to lack of knowledge.)

IX. STANDARDS

Standard is that which is established by authority, custom, or general consent, such as a model example criterion, test, or set of conditions for the measurement of quantity, weight, extent, value, or quality. In addition to the regulations, recommendations dealing with the following subjects should be available.

1. Recommendations for the design and construction of sealed sources and devices containing sealed sources.
2. Recommendations for licensing the manufacture and distribution of generally licensed and exempt devices containing non-AEC radioactive materials.
3. Recommendations for limits of contamination from radioactive materials for working conditions and for release of facilities or equipment to uncontrolled use.
4. Recommendations for the safe operation of accelerators.

(Comment by Mr. Willis: In the area on standards, we had a good deal of discussion on trying to determine what a standard was, so we came up with a definition for our workshop, from which we worked. I must say that we had to have some of the expertise from our Federal agencies on this to have ever come up with wording like that.)

X. SPECIAL STUDIES

State radiation control programs should have sufficient flexibility to undertake special studies of particular concern.

XI. EMERGENCY RESPONSE CAPABILITY

The State should have an emergency response capability for radiation emergencies.

MACHINE PRODUCED RADIATION

I. MEDICAL EXPOSURE

A. Personnel

State radiation control X-ray program personnel should be qualified by training and experience in the field of X-ray hazards and control. Inspection personnel should include qualified college graduates and/or technicians with a minimum of formal two-year training in a school of X-ray technology, in radiation control, or the equivalent.

(Comment by Mr. Willis: Here, we are talking about control personnel at this time. We are not talking about qualifications of users who, in this case, should have adequate instrumentation and should have facilities for calibration and servicing the instruments.)

B. Instrumentation

1. Survey Kit

For each man-equivalent in the field, a survey kit should be provided containing at a minimum an integrating ionization chamber, ionizating rate meter, and glow bars.

2. Calibration and Servicing

There should be a system for calibration and servicing of each radiation detection instrument on a planned schedule. Calibration may be done by the State radiation control program using its own calibration source equipment and procedures or by a commercial instrument calibration and repair service under contract. Such calibration and servicing should be the responsibility of one member of the program staff. Each instrument should bear a tag stating the latest date of servicing and calibration and a calibration curve or correction factors for each detection range.

C. Standards

A State X-radiation control program should adopt or use performance standards which are based on or identical with current Council of State Governments' recommendations, with such modifications as may be deemed necessary by the State, and the electronic product emission performance standards promulgated under Public Law 90-602. The State should regularly provide all owners of X-ray machines with written copies of current standards and/or recommendations applicable to his X-radiation sources. The State should require the owner to inform all employees of their responsibilities for radiation control.

To determine compliance, a State should conduct its own evaluations or inspections.

D. Review of Plans

Each State should require expert review of plans of new or major remodeled installations prior to construction.

E. Inspection Schedule

An inspection system should be established based upon the potential for achieving the greatest human exposure reduction.

F. User Education

The State should encourage, sponsor, or conduct continuing formal educational programs for users or operators of X-ray sources. Specific attention should be given to improving the level of training in radiological health for all operators of X-radiation machines.

G. Source Location and Identification

A State X-ray control program should locate and maintain a record of all X-ray machines.

H. Compliance Determination and Enforcement

A State X-ray control program should be capable of determining and enforcing compliance of all X-ray machines and installations with applicable standards.

II. NONMEDICAL

A. Personnel

A State agency should have personnel qualified by training and experience to conduct a program in the evaluation and control of all nonmedical sources of X-ray equipment and electronic products capable of incidentally emitting X-radiation.

B. Equipment

Radiation equipment and instrumentation should be regularly calibrated and properly maintained.

C. Activities

1. Source Location and Identification

A State agency should locate and maintain a record of all nonmedical X-ray installations.

2. Compliance Determinations

A State agency should conduct its own evaluations and inspections.

3. Standards

A State control program for nonmedical X-ray should adopt for use performance standards which are based on or identical with current Council of State Governments' recommendations, with such modifications as may be deemed necessary by the State, and the electronic product emission standards promulgated under Public Law 90-602.

4. Inspection Schedule

An inspection system should be established based upon the potential for achieving the greatest human exposure reduction.

5. User Education

The State should encourage, sponsor, or conduct continuing formal educational programs for users and operators of X-ray sources. Specific attention should be given to improving the level of training in radiological health for all operators of X-radiation machines.

RADIOACTIVE MATERIALS AND ACCELERATORS

I. ORGANIZATION STRUCTURE AND PROGRAM DIRECTION

Provisions should be made for the control of all radioactive materials.

II. PERSONNEL

For radioactive materials, the State should have a sufficient number of competent professionals with adequate training and experience.

Note: This requirement may be satisfied by a ratio of approximately one man-equivalent per each 100 licenses, with at least one professional competent in the evaluation and control of accelerator hazards.

III. EQUIPMENT

A. Numbers and Types of Equipment

Each program should include adequate field and laboratory instrumentation to detect and measure all types of radiations which could be emitted from radioactive materials or accelerators.

B. Calibration and Servicing

There should be a system for calibration and servicing of each radiation detection instrument on a planned schedule. Calibration may be done by the State radiation control program using its own calibration source, equipment, and procedures or by a commercial instrument calibration and repair service under contract. Such calibration and servicing should be the responsibility of one member of the program staff. Each instrument should bear a tag stating the latest date of servicing and calibration and a calibration curve or correction factors for each detection range.

IV. ACTIVITIES

A. Source Location and Identification

1. Licensing

a. Review of Application

The review of an application for a radioactive materials license must include a detailed health physics analysis of at least the following:

(1) user qualifications

(2) specific uses except broad licenses

(3) types and amounts of radioactive materials requested

(4) facilities and equipment

(5) instrumentation

(6) radiation safety program of user

b. Pre-licensing Evaluation

The program should include a pre-licensing visit of those applications involving a significant risk to the public health and safety.

2. Registration

   All particle accelerators should be registered and/or licensed in accordance with the following specific registration requirements for such devices:

   a. Submission and approval of facility design and engineering designs as related to safety systems.

   b. Submission and approval of operational and emergency procedures.

   c. Pre-operational inspection by State personnel.

3. Unlicensed or Unregistered Sources

   The State should have a planned system of locating unlicensed or unregistered sources of radiation and bringing them into compliance with the State licensing and registration provisions.

B. Compliance Determination and Enforcement

1. Items of noncompliance with accepted State standards or regulations found during inspections should be promptly called to the attention of the licensee or registrant in writing with a requirement that he institute prompt action to correct the cited deficiencies. A record of the corrections made by the licensee or registrant should be maintained.

2. Enforcement actions should be such as to insure complete compliance with appropriate State regulations and accepted standards of safe procedure.

C. Inspection Schedule

A periodic inspection system based upon hazard priority should be established and adhered to for radioactive materials licenses. It should be modified in the light of experience with individual licensees and should undergo frequent evaluation to stay abreast of program needs.

NON-IONIZING RADIATION

The workshop does not have sufficient information at this time to make detailed recommendations in the area of non-ionizing radiation.

I. PERSONNEL

Efforts should be made to develop or acquire capability in the field of non-ionizing radiation.

II. EQUIPMENT

Equipment should be selected for relevance of their measurements to potential health effects.

III. RECOMMENDED ACTIVITIES

A. Legal steps should be initiated to authorize comprehensive program activities in the field of non-ionizing radiations as defined in Public Law 90-602.

B. Procedures should be developed for locating potentially hazardous non-ionizing radiation sources.

C. Standards should be developed and/or adopted to complement those promulgated under Public Law 90-602.

(Continuation of Mr. Willis' remarks) The workshop instructed me to bring this to the attention of the attendant group. The charge was to develop criteria and/or indices of Section 357(B) and (E), Public Law 90-602. During the course of developing these criteria, it became apparent that the greatest hazard to public health in the light of present knowledge is still in the field of medical X-ray exposure, and added priority must be assigned to this field. However, the development, capability, and studies should be initiated in the non-ionizing field.

We feel, from some of the statements that have been made, that we are perhaps overemphasizing the non-ionizing field at this conference. We should definitely go on record as indicating a high priority for the field of medical X-ray, because this is something we definitely have the capability of controlling at this time. We can measure it. We know it is a definite health hazard and consequently in areas where an ample program has not been developed at this time, we strongly recommend that this be given a top priority.

I was also charged by the workshop to present this statement as a resolution to the conference for adoption. Tom, I don't know how you go about doing this, but I am bringing it up right here, and I will leave it up to you as chairman to take it up through the proper rules of order.

The recommendations of Workshop No. 3:

1. That the final workshop document should be distributed to all members of this conference to provide an opportunity for detailed study and comments. We certainly do not want you to blindly buy this document that we have worked on for the past three days. We could not find unity among ourselves, and certainly each of you should have an opportunity to comment upon the criteria which you may be using in the future.

2. That an ad hoc committee should be appointed to continue this workshop study on criteria, including a detailed study of the

philosophy for and indices for measuring progress. In other words, what type of indices are we going to need to tell whether we are moving forward in the control of radiation. This is an old problem that has been around for a long time and it will continue to be around, but as you know, we are being forced to the wall in our fight for funds for radiological health, too. We have got to have good indices which we can use for our State health officers, our budget officers, to show them that we have a need here; that we are carrying on an active program and that we are carrying on an effective program. We feel this would give us additional ammunition if we can come up with a good series of criteria and also the philosophy behind these criteria for making progress.

There are a couple of comments I would like to make concerning the various committees that Roy Parker brought up. How are we going to accomplish liaison with all of these various committees? It seems that we are liable to get lost in a maze of business just like we are here.

Also, as you can see, there is somewhat of a conflict between the recommendations of Workshop No. 3 and Workshop No. 1 on this control authority for radiation being in one agency. Maybe it is just wording, but I think there is some real debate here. Everyone is wanting the same thing, and that is the maximum amount of control with the minimum amount of duplication and bureaucracy, but, at the same time, the legal setup in some States certainly does not enhance itself with this objective.

Discussion (entire group)

DR. PARKER: Bill, I don't know where we got off, but I quite frankly don't see any conflict between Workshop No. 1 and Workshop No. 3, for the simple reason that Workshop No. 1 concerns itself with compatibility. We are simply saying that we are recognizing in pure faith that there are a number of agencies on both the Federal level and the State level involved in the radiation control program. In a number of States there is more than one agency. We would like to see the highest grade of compatibility possible. If this can be achieved by a single State agency, sole performance in a State, fine, well and good, but I can't see that there is a serious conflict between these two concepts.

MR. WILLIS: Our objective is the same, I am sure.

MR. GERUSKY: There appears to be a little bit of concern being generated among the people here. Because of time we are not all going to have the chance to comment, or to get together to review these individual recommendations. However, everyone here will receive a copy of each workshop report as soon as we have time to get back to Washington and get them duplicated and out. This evening, we will have all of the workshop chairmen meet, and get the recommendations of all workshops together in one form. Then, we will present it to the group tomorrow morning.

MR. HARRIS: I would like to call attention to the work already being done by the Professional Examination Service of the American Public Health Association in reviewing position descriptions of State program directors as well as subordinate personnel. I have a report here that shows that 19 States have already used one or more of the examinations in radiological health developed under a contract financed by the United States Public Health Service, Bureau of Radiological Health.

I might also say that the Professional Examination Service is also developing and administering an examination for the schools that are currently training radiological health specialists under grants from both the Atomic Energy Commission and the Public Health Service. Professional Examination Service is now writing Part One of the American Board of Health Physics certifying exams. This organization is deeply involved currently in radiological health personnel evaluations, and if you can find a way to utilize that service, I am sure they would be happy to cooperate with you.

MR. ANDERSON: I think you said that your report indicates that you should concern yourself with all radioactive sources. A better term might be "all sources of radiation." Our thinking is that your committee could come up with suggestions as to possible critical sources of radiation exposures. These would be very welcome. Under the program planning and budgeting system we are supposed to show specific benchmarks of accomplishment. If you have any ideas, we would surely welcome them.

MR. GERUSKY: We could all learn from the Defense Department and their program planning and budgeting, I am sure.

I hope tomorrow morning to be able to ask for a vote from this group on the recommendations of the group. It probably will not be as effective as the approval or disapproval by the various State health officers. However, I think it is important for you people here to be able to raise your hands and say you support or do not support any one of the particular recommendations that are being made by the conference. Your vote will be duly recorded.

MR. FRY: I hate to belabor this point, but you say you want a vote on the reports of these workshops. I don't think very many people here are going to be in a position to vote on the total recommendations of all the workshops.

MR. GERUSKY: What I meant to say was that the workshop chairmen will get together and give you a summary of the recommendations made by each of the individual workshops. You will not be asked to vote on the full report of each individual workshop. I don't think that is fair to any of us.

MR. HALPERIN: I am not sure that there is an urgency to vote today, by this group as a whole or the program directors. I suggest that the reports be put into as cogent a form as possible and presented to you, Tom, and that when they are boiled down into a final document, this document be sent out for review and study. A ballot could be sent out with it for a vote by mail. I don't think anyone here is going to want to commit himself, his State, or his professional reputation, to something he is not sure of at this time.

MR. SCHOFIELD: I want to second those remarks.

MR. LITTLE: Some of us here feel very strongly, I am sure, about some of the recommendations that may be made by the workshops, and if we can agree on some of the resolutions about which we feel very strongly, then I think it will give added strength.

DR. PARKER: I don't really quite understand what the major deterrent is here. If we, as directors of the radiation control program, cannot stand individually on our own two feet here in Montgomery, Alabama, in March, and speak for ourselves, then what are we doing here? We can certainly have our own thoughts. We are not committing the State of Louisiana, the Atomic Energy Commission, the State of Arizona, or the State of Illinois, or any other State, to a particular course of action, but we can certainly voice our opinions and expressions on what we are coming out with here today. So, let's at least determine in which direction we should head. Let's not be reluctant about this thing. Let's go down the road, express our thoughts, and see what we can come up with at the conference. If we cannot speak our voices as directors of radiological health, we have no business being here. Let's go ahead.

We are asking--one of the things we are saying is, "Let's direct the radiation control program on a State and national level." The way to do that is express ourselves, by exchanging consensus of opinion, or a majority or minority report, as you wish, but let's not have this United Nations' majority vote-veto power consideration.

DR. McTAGGART: As much as I hate to, I have to disagree with Roy. I think it is very important that you voice your opinion, but I think you have to know what you are voicing your opinion about, and I don't think that tomorrow or this afternoon enough information can be given to these people to make a vote worthwhile. Now, they can go on record as saying that we will consider these proposals, and approve or disapprove them at a later time, but I would like to remind you that we are recommending that a committee be established representing this group in operational procedure, and unless this group as a whole accepts and recognizes these committees, then they are worthless. I don't think we can do it tomorrow, or I don't think they can do it a week from tomorrow. I think it is going to take some study and some discussion back and forth.

MR. GERUSKY: I don't think we are supposed to be solving all of our problems. I think we are supposed to be discussing them and coming up with possible methods of solution. That doesn't mean that a resolution or an individual recommendation is the final answer. The answer today may be changed tomorrow, and then again it may be changed today.

The chairman of the next workshop, Mr. Robert Siek, had to return to Colorado to handle a problem, so Dr. Bradley from the New York Department of Labor, agreed to take over the chairmanship. He is going to discuss his workshop on the review of current standards for electronic products.

Workshop No. 4

REVIEW OF CURRENT STANDARDS FOR ELECTRONIC PRODUCTS[1]

F. J. Bradley, Ph.D.[2]

LASERS

I. DEFINITION OF PROBLEM

Today, lasers have found varied applications in science, industry, and government. Mass production of lasers has contributed to their use in schools and college laboratories. Seldom has a major discovery been so readily available to so many people in such a short time.

However, there is a real danger that the production and use of lasers are outstripping the understanding of their hazards. It took over 50 years from time of the discovery of radium and X-rays before large-scale safety precautions and intensified medical research reduced the spread of radiation injury.

Lasers produce a concentrated powerful beam of light. The output of a laser directed at a small spot may be 100,000 times as intense as the same area on the surface of the sun.

A laser is essentially a device which applies a source of energy to a gas, liquid, crystal, or other solid substance so electromagnetic radiation of uniform wave length is amplified and emitted in a coherent beam capable of transmitting energy.

Depending upon the material used, the electromagnetic radiation may be in the range of visible, infrared, or ultraviolet light. Substances used in laser production include argon, helium, neon, ruby, and various dyes soluble in water or alcohol.

One of the suppliers of laser devices noted annual sales to more than 50 colleges and 100 high schools in the United States.

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[1] See Appendix A for membership of the workshop.

[2] Principal Radiophysicist, Division of Industrial Hygiene, New York Department of Labor.

II. STANDARDS:

A. THRESHOLDS FOR BIOLOGIC DAMAGE BY LASER RADIATION AT THE RETINA OF THE EYE (6943 A)

Regulation or Code	Threshold Values		
	Q-Switched (Pulse Duration)	Non-Q-Switched (Pulse Duration)	Continuous Wave
U.S. Air Force Regulation 161-24, January 1967	0.125 J/cm^2 (10-100 nanosec.)	--	--
British Ministry Aviation Code of Practices for Laser Systems	0.07 J/cm^2 (30 nanosec.)	0.85 J/cm^2 (200 microsec.)	--
University of California, LRL Hazards Control Quarterly Report 16 and 17, 1964	0.08 J/cm^2 (30 nanosec.)	0.7 - 0.8 J/cm^2 (200 microsec.)	--

B. Recently, the American Conference of Governmental Industrial Hygienists issued a publication, Uniform Industrial Hygiene Codes or Regulations for Laser Installations.

THRESHOLDS FOR BIOLOGIC DAMAGE AT THE RETINA OF THE EYE DERIVED FROM EXPERIMENTAL WORK ON ANIMALS

Type	Wave Length (Angstroms)	Pulse Duration	Level (Joules/cm^2)
Non-Q-Switched	6943	200 microsec.	0.85
Q-Switched	6943	30 nanosec.	0.07
Continuous Wave	White Light	--	6.0

Unprotected personnel shall not be exposed to levels at the cornea of the eye for direct illumination or specular reflection at a wave length of 6943 angstroms in excess of the following values.

MAXIMUM PERMISSIBLE EXPOSURE LEVELS TO THE CORNEA OF THE EYE FROM LASER RADIATION AT 6943 ANGSTROMS

Ambient Lighting Condition	Q-Switched 1 nanosec. - 1 microsec. pulse (J/cm^2)	Non-Q-Switched 1 microsec. - 0.1 sec. pulse (J/cm^2)	Continuous Wave >0.1 sec (W/cm^2)
Daylight (3mm pupil)	5.0×10^{-8}	5.0×10^{-7}	5.0×10^{-5}
Laboratory (5mm pupil)	2.0×10^{-8}	2.0×10^{-7}	2.0×10^{-5}
Night (7mm pupil)	1.0×10^{-8}	1.0×10^{-7}	1.0×10^{-5}

C. The Boeing Company has established a maximum permissible power density exposure of 1.0×10^{-6} watts/cm^2 for continuous wave gas laser radiation at the cornea of the eye.

III. PROBLEM

An obvious problem of standards relating to exposure to laser radiation is that standards differ in consideration of the exposed portion of the eye. The cornea is considered in one case and the retina in others.

No mention is made in existing standards of controlled versus uncontrolled areas. This consideration is necessary to establish control of laser exposure. Other parameters that are not considered are general public versus occupational exposure and genetic versus somatic effects. The cumulative effects of laser radiation are not well documented. In addition, evidence is not presented to allow a uniform development of a "Rem Equivalent" due to differences which may exist in biological effects at frequencies other than 6943 angstroms.

The ease with which a laser device may be built or purchased presents a serious health hazard. Any individual can purchase construction plans for \$10 and with about \$100 worth of materials can build a laser unit.

The action of laser radiation on biological tissue may be divided into two broad areas: (1) those attributed to heat, and (2) those not attributed to heat. These are also referred to as thermal effects and nonlinear effects. Thermal effects usually involve injury to the eye and skin. Since the human eye focuses the laser beam on the retina, retinal damage can be severe and may result in blindness. Therefore, the eye is the critical organ. Laser irradiation of the skin produces lesions resembling thermal burns, such as reddening, swelling, and hemorrhaging. The amount of damage will vary with the intensity and wave length of the irradiation and the degree of pigmentation.

In most laboratory and industrial situations, the laser beam is directed at specific targets. The scattering of the laser beam will depend on the shape and texture of these objects. The hazard to the eye, however, is not necessarily lessened by the reflection of the beam. Even a portion of the reflected laser beam can be harmful when focused on the retina by the lens of the eye.

Additional effort has been directed toward defining the nonlinear (nonthermal) effects of laser radiation in biological systems. Considerable speculation and disagreement exist over the possible mechanisms involved. Some of the mechanisms implicated in the nonlinear effects include: (1) pressure effects from thermal expansion with or without change of phase and shock wave production, (2) ionization and X-ray production, and (3) free radical formation.

Little is known about the potential cumulative effects produced by repeated sub-threshold exposures, either to the eye or the skin. Current data in this area are not sufficient to provide information concerning the possibility of cumulative effects from repeated laser exposures.

Based on information available to the workshop, the included standards appear to be reasonable.

IV. SUMMARY AND CONCLUSIONS

Some of the areas which require further study are as follows:

1. The current standards are based on the 6943 angstroms wave length.
2. Dose-time relationship should be better established and evaluated.
3. Development of safety standards for laser systems by industry in cooperation with official agencies should be an immediate concern.

4. Standards should specify critical organs. That is, the two main ones under consideration right now are the eyes and the skin, and others may be indicated in the future.

5. Laser systems should be registered.

6. Acceptable exempt power densities should be established for registration purposes.

7. Laboratories should be available for standardization and calibration of instruments. This relates to the question of instrumentation and how to measure the values that are established.

MICROWAVES

I. DEFINITION OF PROBLEM

Microwaves are a form of electromagnetic radiation with frequency range of 100 to 100,000 megahertz (MHz). Primary sources of human exposure to microwaves include radar devices, diathermy units, and microwave ovens.

Microwave ovens operate at frequencies of 915 and 2,450 MHz. In 1968, 40,000 microwave ovens were estimated to be in use. If the price of consumer units were to drop to $250 from the current price range of $500 to $1,000 per unit, sales might exceed 500,000 microwave ovens per year.

Diathermy, a method of medical therapy, is still used clinically and is valued by some physicians. It usually utilizes a frequency of 27.12 MHz. Older diathermy units requiring contact electrodes used a frequency of 2450 MHz.

Radars are generally designed to operate at frequencies from 1,000 MHz to 30,000 MHz, or higher.

II. STANDARDS

	Occupancy	Average Power Density
U.S.A.F. (1965)	Unlimited	Less than 10 mW/cm^2
	Limited	10 - 100 mW/cm^2
	Denied	Greater than 100 mW/cm^2
U.S.N. (1966)	Continuous	10 mW/cm^2
	Intermittent	300 mJ/cm^2 for a 30 sec. interval

	Occupancy	Average Power Density
U.S.A.S.I. (1966)		
	0.1 hr. or more	10 mW/cm^2
	0.1 hr. period	1 mW hr/cm^2 (energy density)
California (1967)	(Same as Bell Telephone)	
	potentially hazardous	0.01 W/cm^2
	safe for incidental or occasional exposure	0.001 - 0.01 W/cm^2
	safe for indefinitely prolonged exposure of permanent assignment	0.001 W/cm^2
U.S.S.R. (1958)		
	entire working day	0.01 mW/cm^2
	less than 2 hrs/ working day	0.1 mW/cm^2
	less than 15 or 20 min/working day (protective goggles required)	1.0 mW/cm^2
Royal Radar Establishment - Great Britain (1966)	The maximum permitted exposure of M.O.A. personnel to radio-frequency radiation shall be as shown below:	
	continuous daily exposure of the whole body	10 mW/cm^2
	whole-body exposure to radiation from pulsed modulation systems without a rotating aerial	10 mW/cm^2 averaged over any one second
	whole-body exposure to radiation from rotating aerial systems (including pulsed modulation systems)	10 mW/cm^2 averaged over any one second

Occupancy	Average Power Density
exposure of hand, forearms, feet, and ankles	50 mW/cm^2 averaged over any one second, for periods not exceeding five minutes in any one hour

Considerable discussion has been generated over whether biological effects of microwaves are due to the increase in the average kinetic energy of molecules of the tissue and thereby effectively producing a heat injury or in addition, whether effects can be produced by microwaves where there is no heating of the tissues. For frequencies of 1,000 to 10,000 megahertz, microwaves have been shown to produce cataracts,with indications that the most critical level is at 3,000 megahertz, which is near that used in commercial ovens. The risk of producing children with mongolism is reported to be greater for men formerly employed as radar technicians, implying possibilities of harmful genetic effects. Needs for further study is indicated by the higher frequency of luekemia in children with mongolism.

Another aspect that has attracted attention is the possible neurological effect of microwave radiation. The Soviet scientist, Gordon, has reported that after irradiation with microwaves at 5 to 10 mW/cm^2 the delay between stimulus and conditioned reflex in dogs increased and the employment of a larger stimulus became necessary. In addition, histological examinations of brain tissue revealed physiological and chemical changes such as globular concentrations of acetylcholine along nerve fibers. Dr. Susan Korbel of the University of Arkansas also reports that after irradiation of Sprague-Dawly laboratory rats with microwaves at 5 mW/cm^2 the rats displayed a hyperactivity followed by hypoactivity. She is currently investigating concentrations of acetylcholine along nerve fibers in the rat's brain.

Two other studies in the United States of radar laboratory personnel were designed to detect microwave effects on the lens of the eye. The results of these studies did not reveal any clinical findings directly attributable to microwave exposure with the exception of possible changes in the differential blood counts. One study involving 800 microwave workers was designed to define the incidence of lenticular injury. Initial indications were that no differences existed in the incidence of eye pathology in the two groups of workers examined. More recently, however, incipient and overt cataracts have been observed in the microwave-exposed population. In the study, 91 cases of lens damage by microwaves were discovered. Thirty-six of these cases were classified clinically as cataracts and the other 55 cases exhibited minimal changes, e.g., roughening, thickening, and early opacification of the postular capsule of the lens. According to the investigator, the threshold power density seems to be 100 milliwatts per cm^2, although total energy and rate of delivery were not reported.

III. SUMMARY

Microwave ovens are being built with interlock systems as a primary safety feature. Industry must take a basic look at this interlock concept, because the interlocks are being used as a convenience mechanism for activating and deactivating devices, and not for the original purpose they were intended.

Currently, there seems to be a lack of suitable survey instrumentation. Nationwide calibration facilities are not available and the application of the near-field versus far-field correction factors is not fully understood. This is especially acute with respect to the microwave oven, because you have the source right in the oven and you are usually quite close to it, while with most radar surveys, you are normally in the far field.

Present experience indicates a lack of manufacturing and installation requirements, which could alleviate inherent exposure of people. Further, there has not been an effort to establish a control area in microwave installations, and present standards do not consider the general population versus occupationally exposed individuals.

The standards reviewed stipulate exposure rates ranging from 0.01 to 300 milliwatts per square centimeter, a difference of approximately 10^4. In addition, with respect to exposure limits that have been established, there should be a correlation between these limits and the different frequencies that are really different sources in their biological effects.

Microwave exposures have been reported to result in both somatic and genetic effects on the biological system.

In looking at these exposure standards, it is noted that very few of these relate to microwave exposures to the different parts of the body.

IV. CONCLUSIONS

A. Establish 1.0 milliwatt per square centimeter as the maximum exposure rate for microwaves until evidence suggests otherwise; approximately mid-range between 0.01 and 300 milliwatts per square centimeter value.

B. Establish a control area where exposure rates are above 1.0 milliwatt per square centimeter.

C. Further attention should be given to the genetic and somatic response and the time-dose relationship at various wave lengths.

D. Standards for safety must be developed for the manufacture and installation of microwave devices by industry in cooperation with the official government agency, and immediate attention should be given to safety standards for doors and interlocks on microwave ovens.

E. Establish facilities for standardization and calibration of instruments.

F. Establish suitable techniques for surveying microwave devices.

G. Develop suitable instrumentation.

These last three can be stated for all types of ionizing and non-ionizing radiation.

STANDARDS FOR IONIZING RADIATION FROM ELECTRONIC PRODUCTS

I. EXISTING STANDARDS

New York Department of Labor Industrial Code, Rule 38, "Radiation Protection":

> "Exemption No. 11. Radiation equipment which by reason of its design cannot emit radiation at a level which, when measured two inches from the surface of such equipment with all external shielding removed, exceeds a rate of 0.5 millirem in an hour. This exemption does not apply to the testing or servicing of such equipment during the production thereof."

A similar exemption exists in the New York State and New York City Department of Health, Ionizing Radiation Codes, and Public Health Service document and Council of State Government Model Code.

II. IDENTIFICATION OF PROBLEM AREAS

A. There is a need to identify those electronic products that require immediate manufacturing standards to implement Public Law 90-602. At present the following product standards are in the process of formulation by the Bureau of Radiological Health:

1. Color TV sets,

2. X-ray diffraction units, and

3. Particle accelerators operating at voltages greater than 1 MeV.

B. It is desirable to clarify the responsibility of the component part manufacturer, such as the manufacturer of high voltage electronic tubes, and the responsibility of the manufacturer of a finished product capable of producing ionizing radiation either incidently or deliberately.

C. The expected useful life of an electronic product should be an important consideration in setting of electronic product standards. The standard must take into account subsequent handling, repair, and even modification that could conceivably alter the built-in factory protection. A printed statement on the product concerning the useful life of the built-in safeguards may be sufficient.

III. SUMMARY AND CONCLUSIONS

A. It is necessary to establish a priority of electronic products that require manufacturing standards.

B. There are no manufacturers' standards which meet established performance standards.

C. The component manufacturers' responsibility should be established in relation to the responsibility of the manufacturer of a finished electronic product under Public Law 90-602.

D. It will be necessary to define the average lifetime of an electronic product over which it should meet the product standard and this lifetime should be specified in the standard.

E. The Bureau of Radiological Health must establish effective procedures for the development of manufacturers' standards and their implementation. This activity should be given a high priority.

F. A format should be established to coordinate existing State Radiation Protection Programs and the Federal Surveillance Programs to implement Public Law 90-602 standards.

Discussion (entire group)

MR. ANDERSON: My only comment is that I see nothing in this report inconsistent with our program objective.

MR. FARKAS: I have a question about the lifetime averages testified to. Does that mean during our lifetime?

DR. BRADLEY: No, no, what we were attempting to bring out was the problem, for example, of the microwave oven. The manufactured product may meet a manufacturing standard when it leaves the factory, but will it meet the same standard during the whole life of the device. There is no doubt that it should be the life of the device, but this must be stipulated in the manufacturing standards.

Workshop No. 5

REVIEW OF CURRENT STANDARDS FOR CONTROL OF NON-ATOMIC ENERGY COMMISSION MATERIAL[1]

Henry C. Briggs[2]

Since our workshop was assigned to the study of non-agreement material, I guess we might title it the non-agreement workshop. Actually, we came to quite a bit of an agreement and I want to read off a statement of our result on the non-Atomic Energy Commission materials.

I. INTRODUCTION

The report of this work group addresses itself to the problem of governmental control of radioactive materials other than by-product, source, and special nuclear materials as defined by the Atomic Energy Act of 1954, as amended. The latter materials are presently controlled by the Atomic Energy Commission and Agreement States under licensing programs. Historically, radium and accelerator-produced radionuclides have been within the jurisdiction of individual State programs, and have not come under the control of the Atomic Energy Commission.

Most of the States which have entered into agreements with the Atomic Energy Commission pursuant to section 274 of the Atomic Energy Act have included all radioactive materials under the same licensing program. The work group feels that such uniform control is desirable and it is the concensus of the work group that radium should not be treated in a singular manner simply because of its long history of usage.

II. CURRENT REGULATORY EXPERIENCE

Since the model regulations of the Council of State Governments have been used extensively by States entering into agreements with the Atomic Energy Commission, the work group made a comprehensive review of these regulations with respect to applicability to non-Atomic Energy Commission controlled radioactive materials. Recent revisions to the Atomic Energy Commission regulations will result in changes to the model regulations. The effect of these revisions has been examined. The following comments refer to various sections of the model regulations:

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[1] See Appendix A for membership of the workshop.

[2] Radiation Safety Officer, University of Indiana. Formerly, Director, Division of Radiological Health, Indiana State Board of Health.

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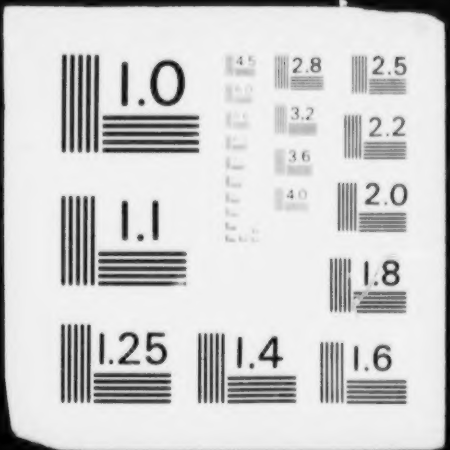

1. In Part F, the current leak test requirement for radium sources is inadequate and a new test which will detect radon leakage should be specified in the use of sealed radium sources in the healing arts. This should be a performance type of standard permitting the use of various acceptable methods.

2. Although radium has been used for a number of years in luminous compounds applied to consumer products, the work group recommends that its use be reevaluated in the same context as the use of tritium and promethium-147. Due consideration should be given to complete elimination of radium in luminous compounds with a provision allowing for reasonable time for manufacturers to convert to other radioisotopes.

3. Surveys have indicated that radium contamination exists in watch repair shops where timepiece dials and hands have been scraped and refurbished. The work group discussed the need for regulating the use of radium in these facilities; however, present manpower and administrative resources preclude the recommendation of an immediate control program. It is recommended that the use of radium in such circumstances be investigated to determine whether a regulatory program is justified.

4. The Atomic Energy Commission has proposed to exempt small quantities of radioactive materials from regulatory control excluding long-lived alpha emitters. This proposal will abolish the present general license schedule in 10CFR 31.100, Schedule A, of the Atomic Energy Commission regulations (Part B, Schedule B of the Council of State Governments' Model Regulations), and establish a new schedule of exempt quantities in 10CFR 30.71. The work group recommends that radium be treated in the same manner as other long-lived alpha-emitting radionuclides and, therefore, not have an exempt quantity. Consideration should be given to "grandfathering" sources of radium falling within the present Schedule B; however, no new sources of this magnitude would be permitted without specific license. Provision should be made to include small quantities of radium as calibrated and reference sources in B.22(e) of the model regulations.

5. Although several members of the work group disagree with the basic concept of a general license for the medical use (B.22(g) of the model regulations) of radioactive materials, it was felt that adding appropriate accelerator-produced radioactive materials to the list of approved radionuclides

contained in the general license, when such radionuclides have been demonstrated to be safe and effective, may result in lower radiation doses to patients than byproduct materials currently included in the general license.

III. INADEQUACIES IN PRESENT CONTROL

A. Radiation Control in Federal Facilities

The work group recognizes that radiation control in Federal installations such as Veterans Administration hospitals, Department of Defense facilities, United States Public Health Service hospitals, etc., is presently not subject to the same regulatory control as similar radiation facilities in civilian installations.

B. Federal Surplus Property

The disposal of radioactive material through government surplus channels has been identified as a source of unnecessary radiation exposure to the general public. The work group feels that this exposure is unjustifiable and the uncontrolled distribution to civilian use of such surplus be eliminated.

C. Control by the Food and Drug Administration

The use of accelerator-produced radioactive materials for medical diagnosis and therapy in non-Agreement States has been identified as a possible void in effective regulatory control. As the Food and Drug Administration is currently not able to evaluate and approve the use of these materials in the same manner that byproduct materials are reviewed and approved by the Atomic Energy Commission under the exemption extended to it by the Food and Drug Administration, some method of review and approval of these materials must be instituted. The work group recommends development of regional human-use committees composed of qualified experts in nuclear medicine and allied health sciences to review and approve the use of these materials in medical situations.

D. Manufacture and Distribution of Radium Containing Sources

As the Atomic Energy Commission licenses the manufacture and distribution of consumer products and exempt devices containing radioactive materials under its jurisdiction, it is recommended that legislation be enacted to give the Secretary of Health, Education, and Welfare, similar authority to license the manufacture and distribution of radium-containing consumer products and exempt devices. The licensure of such devices, other than consumer products and exempt devices, would remain the exclusive jurisdiction of the individual States.

E. Manpower

As State radiation control programs have been and continue to be faced with a variety of problems in the recruitment and training of professional staff, direct assistance in the form of State assignees from the Bureau of Radiological Health is considered desirable and should be continued.

IV. RECOMMENDATIONS

A. The use of non-Atomic Energy Commission materials should be controlled by the State licensing program. As a minimum, and presumably an intermediate program, registration is required.

B. Revisions of the model regulations of the Council of State Governments should be made to update these regulations for use in regulating non-Atomic Energy Commission material. Radium should not be allowed special exemptions for future applications. I will get back to this subject. We are recommending several items in the model regulations, including a study.

C. Representation of State and Federal radiation control officials should be included on the National Council on Radiation Protection and Measurements. Reports of this Council should be issued as expeditiously as possible.

D. Federal installations (this is in some other group's report) should be subject to the same radiation control requirements as are applicable to non-Governmental facilities.

E. The uncontrolled disposal of radioactive materials to civilian users through Government surplus channels should be eliminated.

F. Regional human-use committees should be established for consultation with the States for assistance, review, and approval of uses of non-Atomic Energy Commission radioactive materials in medicine.

G. Federal legislation should be enacted to authorize the establishment of performance standards for the manufacture and distribution of radioactive sources and devices containing non-Atomic Energy Commission material.

H. Assistance to the State radiological control program should be provided to the States by enhancement of the State assignee program of the Bureau of Radiological Health.

Discussion (entire group)

MR. WILMS: I think it would be wrong for us not to exempt small amounts of radium as apparently one of the recommendations does. Your statement was, I think that we treat radium like all of the alpha radioactive material, and therefore we should not have an exempt quantity. I support the idea of getting rid of general licensing. Either we should exempt or specifically license, and I think we can set an acceptable level for long-life alpha emitters. But I would forget all of this extensive administrative rigamarole that we go through for general license.

MR. SNOW: One of the recommendations touched on membership of State and Federal officials in the National Council on Radiation Protection and Measurements (NCRP). Although there are State and Federal officials on the Council, the criterion for membership is the expertise that these individuals command by virtue of their professional backgrounds. I know of no mechanism, even though it might take the form of a recommendation coming out of this meeting, to command the concensus of the group to the NCRP. This would be a departure from the practices of the NCRP.

MR. GERUSKY: The NCRP does attempt to obtain capable people from State and Federal agencies.

DR. WILLIAMS: I think that is the interpretation that you must get. But the criterion is based upon their expertise.

MR. McHARD: I just wanted to mention that with respect to the third recommendation on radium, concerning watch repair shops, we are presently conducting a study on watch repairmen, and hope that when this is finished we will have the data we need to determine just exactly what the hazards to these horologists are. I cannot report any results today because we have made no judgment. We just collected a lot of information, that is all.

MR. GERUSKY: Some of these State and local programs cannot be included in this type of review. Our Conference now has the opportunity to start transmitting some of this data to each other so that we do not duplicate the work that is done in each individual State or local program. That is one of the greatest things we can accomplish. Are there any other questions, comments, or suggestions?

DR. WILLIAMS: Sam Ingraham sort of pushed me into this. I will reiterate the fact that the National Council on Radiation Protection and Measurements is an organization, the membership of which never, ever represented anybody, any group, or any organization. The NCRP was formed in 1946, as a combination and expansion of three previous advisory committees; here again, it was not made up of people representing anybody but themselves as individuals, not organizations; but rather being chosen as people who could, and hopefully would, bring to the group ideas or attitudes which would reflect those of the various types of people who would be affected by the recommendations of the NCRP. Dale Trout[3] was listed in the Bureau of Standards Handbooks as some manufacturer's representative but he did not represent the Electrical Manufacturers Association. He did bring to the NCRP deliberations and considerations and a background of familiarity with the needs of that group, and it is in that sense of breadth and depth of its membership that the National Council on Radiation Protection and Measurements continues to operate. Its numbers are now elected by the membership, and elected on the basis of trying to assure, and trying to insure, that every deliberation that they enter into has the widest possible background of experience, but not representation.

MR. GERUSKY: The next workshop was concerned with the control of electronic products at the State level. Mr. Gerald Parker of Massachusetts is Chairman.

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[3] Professor of Radiological Physics, Oregon State University.

Workshop No. 6

CONTROL OF ELECTRONIC PRODUCTS AT THE STATE LEVEL[1]

Gerald S. Parker[2]

In the area of ionizing radiation, 52 States and terretories have authority to regulate. Forty-five of these States have adopted regulations, and 44 of the States and territories have permissive statutes to enter into an agreement with the Atomic Energy Commission. Nineteen of the 44 are presently Agreement States.

In the area of non-ionizing radiaton, 14 of the States and territories have either the authority to regulate or have prepared and introduced enabling legislation, to include all types of electronic products, or just lasers.

As it is the responsibility of individual States to provide for the health and safety of its people, it is imperative that the States take appropriate action to meet these responsibilities. In this respect, every State should have legislative authority to regulate radiation from electronic products. This should be accomplished by extension and amendment of existing legislation, or by the enactment of new specific acts or laws. Every effort should be made to insure uniformity and compatibility of these laws and regulations among the different States. This uniformity is essential for the adequate implementation of Public Law 90-602.

The existing State and local programs, including control of the hazards of ionizing radiation from electronic products, must be continued and expanded to include the control of hazards from non-ionizing radiation. In the area of ionizing radiation, and particularly in the control of X-rays, the effort must be continued and expanded. The Public Health Service population X-ray exposure study indicates that the genetically significant dose to each individual in America from medical and dental X-rays was 55 mrem per year. This dose can be reduced dramatically by changing some physical and technical factors. The education effort must be continued so that the injudicious use of X-ray will be eliminated.

It was thought by our group that each State should adopt a uniform regulation requiring every person to notify the State radiation control agency of the sale, trade or transfer of X-ray equipment, and also require that all used equipment meet applicable State standards. The need for notification of sale, trade, or transfer of electronic products shall be determined on a product-by-product basis after the Federal Government establishes performance standards for the various products. If such need is determined, each State should adopt applicable uniform regulations.

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[1] See Appendix A for membership of the workshop.

[2] Assistant to the Commissioner, Massachusetts Department of Public Health.

Machines that emit ionizing radiation other than medical and dental X-ray are also controlled presently in many of the States. The Environmental Control Administration must be in a position to support the existing State programs and to initiate continuing State support in the area of non-ionizing radiation.

Now, before the States take any action in the area of non-ionizing radiation, the potential hazards of this radiation must be defined. To accomplish this, the Environmental Control Administration should:

1. Enter into an intensive research program to define the threshold limits for biological damage to the various parts of the body from electronic product radiation.

2. Develop standardized instrumentation and measurement techniques which will insure reproducible measurements.

3. Develop an adequate cadre of State personnel in electronic product work as previously done with ionizing radiation. This would include preparation of short-term courses and support of training at universities through institutional grants.

In developing the items, the Environmental Control Administration should consult with the States in order that they may take advantage of the States' capabilities. The administration should maintain close liaison with the States with reference to their research and training activities. The States for their part should keep the Environmental Control Administration informed of their activities in the electronic products field and the results of all surveys should be made available to the administration.

It has long been recognized by Congress that the States are primarily responsible for the implementation of programs directly affecting the public. Direct financial support must be forthcoming from the Environmental Control Administration in the form of long-term grants and/or contracts to develop and maintain viable State programs for the control of the hazards of non-ionizing radiation from electronic products. Without this support, it will be difficult for the States to adequately carry out their responsibility of protecting the health and welfare of the public.

In conclusion, our workshop recommends the following:

1. Each State shall seek legislative authority to control the hazards from non-ionizing radiation from electronic products.

2. The Secretary of Health, Education and Welfare, should support research, training, and implementation processes by States and Federal agencies regarding electronic product non-ionizing radiation.

3. A committee appointed by the Conference of Radiation Control Program Directors should participate in the preparation of the standards to be adopted under the provisions of Public Law 90-602.

4. Each State should adopt a uniform regulation requiring every person to notify the State radiation control agency of the sale, trade, or transfer of X-ray equipment, and also require that all used equipment meet applicable State standards. The need for notification of sale, trade, or transfer of other electronic products would be determined on a product-by-product basis.

5. Every effort should be made to insure uniformity and compatibility of regulations among the different States by the adoption of a model code of regulations for the control of hazards from radiation from electronic products.

Discussion (entire group)

DR. PARKER: You made a proposal that the Environmental Control Administration support by funds, programs for the control of non-ionizing radiation of electronic products. I would suggest that we also include the term "ionizing radiation." We feel that the State and local programs must be continued and expanded, and the Environmental Control Administration must be in a position to support these existing State programs. I think we want to separate the two. We don't want the funds that may become available to be thrown into the background. We want these to be categorical grants to the States for radiation work. What has already been done we can't undo, but let's separate the two of them.

MR. GERUSKY: Section 602 does also cover ionizing radiation, and if grants should become available under Public Law 90-602, it ought to cover both ionizing and non-ionizing radiation. Do we have any comments on that?

DR. McMARTIN: Categorical grants were eliminated at the request of the States' attorney or health officer with the passage of Public Law 89-749 You fellows have the right to object to it and I hope that you are granted this right, but please understand that the authority was given to the comprehensive health planning and the grants that are involved in it. The people in the States have been thinking about this for a long time. Categorical grants, I think, assisted materially in starting you fellows along the road in developing some of the programs that otherwise would still be quite a ways away from doing very much at all. However, I don't believe at the present time that you have to be as concerned as you were five or eight years ago, because some of you now are spending considerably more of locally appropriated funds in your program. The categorical grant only constituted a small proportion, around 30 or 32 percent, which I think is a compliment to you and to the States. Where you have a good program, you are not going to be in real trouble selling the idea to your health officer any more than you would be if you were trying to get matching grants because they would be that. On the other hand, this does not stop Congress from appropriating money for special services, grants, or contracts permitting the Federal Government to purchase information or to support people, either one of your staff or one of ours in the State, to do a special job.

MR. ANDERSON: I think the workshop report brought out one important thing, and that had to do with what kind of health problems we in fact have with non-ionizing radiation. Now, as our first step in looking at this, we are doing some in-house research work, but we are going to have a conference of people that are engaged in the area of the biological effects of non-ionizing radiation to see what kind of ball game we are in, because I think none of us really know at this point. There is no good consolidation of information in this area. We are going to try to get this, so then maybe we can talk from a firmer platform.

Workshop No. 7

PERFORMANCE STANDARDS FOR RADIATION USERS[1]

William H. Aaroe[2]

Our workshop, after much discussion, decided that there is a need for changing standards for users and prescribers of radiation. We have devised the following plan of action.

I. TECHNOLOGISTS

A. Although not specifically covered in Public Law 90-602, because of the present high-level interest in X-ray technologist licensing legislation, the following suggestion is offered in the interest of uniformity.

Following appropriate consultation among the Public Health Service, States, and professional societies, model legislation for licensing X-ray technologists should be presented as soon as possible to the Conference of Radiation Control Program Directors for comment.

B. With respect to the nonmedical use of X-ray:

1. The Public Health Service cooperatively with the States and all others affected shall develop standards for the training of nonmedical X-ray technicians by July 1, 1971.

2. The Public Health Service shall establish a nationwide system for approving the training of nonmedical X-ray technologists to assist State regulatory programs.

3. The Public Health Service cooperatively with the States shall study the feasibility of licensing nonmedical X-ray technicians.

C. The Public Health Service shall evaluate the training and licensing of physical therapists by July 1, 1971, with special emphasis on non-ionizing radiation physics, biology, and protection. Copies of the evaluation report with recommendations should be sent to all States (only two States do not license).

D. The Public Health Service cooperatively with the States, Atomic Energy Commission, and others affected, should develop by July 1, 1971:

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[1] See Appendix A for membership of the workshop.

[2] Chief, Radiological Health Program, New Jersey Department of Health.

1. Training standards for users of radioactive materials in nuclear medicine.
2. Training standards for nonmedical users of radioactive materials.
3. An evaluation of the need for licensing individuals in categories (1) and (2) above.

II. LICENSED PRACTITIONERS

A. A workshop committee shall be appointed at this meeting to evaluate Dr. Reynold F. Brown's proposal for Appropriate Standards for X-ray Machine Operators as it pertains to licensed practitioners. This report shall be submitted to the Bureau of Radiological Health by January 1, 1970.

B. The Bureau of Radiological Health, together with all affected professional societies and representatives from States, shall evaluate the current status of radiological health education provided in schools of the healing arts. The report rendered shall be distributed by the Bureau of Radiological Health by July 1, 1970.

C. The Bureau of Radiological Health shall prepare a questionnaire to determine the current status of questions on radiological health included in State and national board examinations. Appropriate State and national agencies shall be requested to supply the information and the Bureau of Radiological Health will distribute a report of all participating States by January 1, 1971.

D. States shall be urged to increase in-service training for all radiation users.

III. SPECIAL RECOMMENDATIONS

A. The Public Health Service should sponsor annual meetings with the State radiological health program directors.

B. The Public Health Service shall sponsor the meetings of committees which are called for by this workshop and make any resultant recommendations available to all States.

Discussion (entire group)

MR. HARRIS: Again, may I suggest that you consider contacting the Professional Examination Service of the American Public Health Association. They are currently writing national exams in medicine, physiotherapy, vocational rehabilitation and many other fields which may be affected by this legislation, and they are using radiological health questions from radiological health series that I mentioned earlier. I think they would be very cooperative in this study.

MR. ANDERSON: Dr. William Cole is very active in this area. Unfortunately, I believe he has left for Washington.

Workshop No. 8

INSPECTIONS AND RECORDS, UNIFORMITY AND UTILIZATION[1]

Richard M. Fry[2]

This workshop discussed problems relating to the total radiological health program as it deals with official inspections conducted and records maintained by all concerned Governmental agencies.

In this report, an inspection is defined as a critical observation of the use and/or examination of source(s) of radiation and/or its environs to determine compliance with recommendations or legal standards established by an appropriate authority.

The workshop makes the following recommendations regarding inspections:

1. That the inspection responsibilities for the overall radiological health programs and the implementation of Public Law 90-602 be delegated to the State and local radiation control agencies to the degree that they are willing and capable. This delegation of authority for inspections should be negotiated with the individual agencies.

2. That all radiation control inspection activities be coordinated and include:

    a. A uniform training program for persons performing inspections.

    b. A periodic review of inspection procedures.

    c. A minimum set of data.

    d. Standard collection, collation, and evaluation procedures to insure uniformity of interpretation of the information.

3. That contracts and/or grants for radiation control activities be negotiated in such a manner that new activities will complement the existing ones. To accomplish this, a special system of incentive grants and/or contracts be established to complement existing State appropriations and Federal program support grants.

4. That in the process of establishing national program priorities concerning inspections, the Secretary of the Department of Health, Education, and Welfare, consider the priorities established by the States under their comprehensive health plans.

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[1] See Appendix A for membership of the workshop.

[2] Director, Radiological Health Program, Kentucky Department of Health.

5. That a quality control service be developed by the Bureau of Radiological Health and shared with the States to assure uniform and accurate inspection data on the basic radiation control parameters in all areas of radiation control.

In this report a record is defined as all materials that contribute to the documentation of a specific activity or action, including correspondence, inspection and survey data, studies, and support information that are developed and maintained in a matter that is defensible and accurate.

The workshop makes the following recommendations regarding records:

1. That certain types of basic information must be kept and be readily retrievable to insure collation and evaluation of selected essential information on a compatible nationwide basis. This does not imply a limitation on the collection of additional information by the individual jurisdictions for specific studies or program purposes.

2. That the following categories of records be maintained:

   a. Registry of location and identification of radiation sources.

   b. Compliance with recognized standards.

   c. Incidents involving radiation sources.

3. That a periodic review of the utilization of records be conducted.

4. That information be exchanged between concerned governmental agencies.

5. That concerned regulatory agencies consult appropriate legal counsel to determine the format of records to insure that they may be used as evidence for compliance proceedings.

The workshop makes the general recommendation that a committee be established, including individuals from local, State, and Federal radiation control programs, to help implement the recommendations of the workshop on inspections and records.

Discussion (entire group)

MR. ANDERSON: I am an old milk inspector from several years back, and in connection with their record keeping in milk pasteurization, for example, which required quite a few detailed records in their quality and control, what I was wondering is, is the workshop considering this matter of inplant quality and control in connection with record keeping?

MR. FRY: We did in fact discuss that at considerable length, that is the use of what we called industry records. We limited our final report to governmental records, but with the understanding that such records would be kept with the minimum duplication and full utilization of the quality control records that would be maintained by industry.

Workshop No. 9

STATE VERSUS FEDERAL SURVEILLANCE NETWORKS[1]

Heinz G. Wilms[2]

We did consider the question of surveillance of non-ionizing radiation in the environment as well as the ionizing radiation environmental surveillance activities. Since we knew nothing about the effect of non-ionizing radiation on the environment, it did not enter into the discussion too much with the exception of a recommendation.

I. INTRODUCTION

The environmental surveillance activities by both Federal and State health agencies in the past have been carried out in relation to fallout from atmospheric nuclear weapons test activities to determine the radioactivity in air, milk, water, and food. In 1962 the Nuclear Test Ban Treaty was negotiated. In the years following the treaty, the levels of radioactivity in the environment have decreased annually until the levels in the principal vectors appear to be constant with respect to the critical nuclides of strontium and cesium. Periodically China and France, who are not signatory to the Test Ban Treaty, conduct atmospheric tests which result in short term intrusions of radioactivity that can be detected by surveillance networks. However, recent megaton tests by China have not been detected.

II. WHAT AN ENVIRONMENTAL SURVEILLANCE PROGRAM SHOULD DO

A surveillance system should provide public health officials with information necessary to evaluate the health impact of environmental contamination. Such information is used to determine the optimum procedures for implementation of remedial action. Concurrently, research programs should investigate: (1) how contamination is injected into the environment; (2) its pathway; (3) the method and significance of radionuclide concentration; and (4) the relative impact this contamination has on the public health in relation to other sources of radiation. Therefore any environmental surveillance program should be designed to have the following capabilities:

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[1] See Appendix A for membership of the workshop.

[2] Chief, State Support Section, Office of Regional Operations, Bureau of Radiological Health, Public Health Service. Formerly, Director, Division of Environmental Safety, Nebraska Department of Health.

A. Provide for rapid alert of potential problems; initiation of appropriate response including increased surveillance and protective action

B. Provide information on existing concentrations of radionuclides in important environmental media.

C. Provide evaluation of public health importance of existing levels of radionuclides.

III. SURVEILLANCE IN PERSPECTIVE

Every radiological health program is presently faced with additional responsibilities and duties which are making a demand for the program dollar. Also, because of the shortage of funds both at the Federal and State level, it is becoming increasingly difficult to justify expenditures of large amounts of monies for environmental surveillance programs which are only showing small changes above background levels.

Because of this demand for monies it is necessary that we reevaluate our environmental surveillance programs and arrive at a decision as to which activities must be maintained to give us meaningful data for our radiation control programs and which activities should be reduced to a standby capability. Whatever the revised surveillance activity becomes, it should maintain the capability to identify and assess new sources of population exposure from the environment.

IV. THE FUTURE NEEDS FOR ENVIRONMENTAL SURVEILLANCE PROGRAMS

Recent nuclear weapons or device tests have released to the environment a greatly reduced amount of fission products. In planning for surveillance activities in the future, health agencies must be aware of the changes in the international situation related to the Test Ban Treaty, and the Nuclear Nonproliferation Treaty, in making long-range plans for surveillance of radionuclides.

The years ahead will bring increased uses of atomic energy for the generation of electric power, for medicine, education and research, for many industrial applications, and for propulsion systems. The uses of nuclear explosions for peaceful purposes are just beginning and may become important in future years.

The surveillance activities needed to measure sources of environmental radioactivity must now be directed toward those specific sources of radioactivity that are being developed and promoted.

In essence, this means that surveillance activities should now be source oriented rather than solely for the purpose of detecting fallout from weapons test activities. It is recognized that this type of surveillance activity will tend to reduce the level of effort by the Federal Government on a nationwide basis and increase the surveillance activities by individual States that have specific sources of environmental contamination.

Public Law 90-602 has recognized potential hazards of non-ionizing radiation. Agencies which are presently responsible for environmental surveillance of ionizing radiation should also have responsibilities for the environmental surveillance of the non-ionizing radiations emitted from such sources as lasers, microwave devices, etc. Although procedures for environmental monitoring of these types of non-ionizing radiation have not been developed, surveillance agencies should be aware of new technology and be prepared to respond should the need arise.

V. RECOMMENDATIONS

Based on the information available, the workshop concludes there needs to be a reorientation of existing environmental surveillance programs to specific sources. In the past the principal area of concern was fallout. This is no longer the case. Reorientation of specific sources will eliminate unnecessary duplication of Federal and State efforts. Therefore, to make most efficient and effective use of available resources the following recommendations are made:

A. The State environmental surveillance program should be adjusted to become source oriented. It must be flexible and responsive to need as new sources are identified. Certain environmental data from this system should be transmitted to the Bureau for inclusion in its monthly report of nationwide data.

B. Where States do not have environmental monitoring systems that can respond to an emergency situation or other need for environmental sampling activities, these States should be stimulated to develop these capabilities and maintain them on a standby basis.

C. Under the provisions of Section 356(b)(2) of Public Law 90-602, States should be encouraged to apply for grants to conduct special studies needed to develop the methodology for evaluating environmental effects from sources of non-ionizing radiation.

D. The Bureau's Pasteurized Milk Network should be discontinued as a Federal program to measure radioactivity in milk resulting from worldwide fallout. In place thereof should be State milk surveillance programs to monitor releases of radioactivity from specific sources. However, in those States which do not have specific sources, the Bureau' s Pasteurized Milk Network may be placed on a stand-by basis. The Bureau's Regional Laboratories should maintain the capability for analysis of milk on a nationwide basis so that it can be activated should there be a projected significant rise in the atmospheric levels over an extended period of time.

E. Because the Bureau's Institutional Total Diet Network is fallout oriented, it is not consistent with the source-related concept. Therefore, this network should be discontinued.

F. There is a continuing need to have information readily available at the national level on radioactivity in the air that is responsive to intrusions of radioactivity into the atmosphere. Consequently, a minimal Radiation Alert Network should be maintained by the Bureau of Radiological Health.

G. The Bureau of Radiological Health should assist in evaluating the State capabilities for environmental surveillance within the context of these recommendations. Where duplication of Federal and State activities are evident, the Bureau should negotiate with the States involved to eliminate this overlap by utilizing State source-oriented systems where possible.

H. A joint Federal-State effort should be utilized to encourage the Federal Radiation Council to establish appropriate radiation protection guides for radionuclides such as tritium, plutonium, krypton, and other radionuclides of public health concern.

I. The Bureau should act as the data collecting agency and should analyze, collate, and interpret the environmental surveillance data to:

1. Assess general population exposure due to environmental radiation.
2. Compile reports of trends in environmental radiation and distribute these to the interested agencies.
3. Act as a central repository for environmental sampling data.

4. Publish these data.

J. The Bureau should assume a leadership role in identifying new environmental contamination problems and supply technical assistance to States by development of improved analytical techniques as they may apply to new sources of environmental contamination.

K. Bureau of Radiological Health regional laboratories should:

1. Evaluate and standardize sample collection techniques.

2. Establish a system of exchanging split samples with those environmental surveillance laboratories involved to assure accurate and compatible data.

3. Offer on-the-job training to State laboratory technicians to develop increased competence and efficiency in the State radiological laboratories. This will tend to produce uniformity in procedures and standardization of data from State programs.

4. Maintain capabilities to respond to emergency situations that would require rapid analysis of large quantities of environmental samples.

L. For purposes of national surveillance, all networks whether operated by the Federal Government or the States, should be regarded as a single system. Consequently, an advisory committee composed of three representatives from States, and two from Federal agencies should be formed to review the adequacy of surveillance systems and suggest changes or modifications that may be required to maintain a viable and responsive environmental surveillance system. This committee should develop reports of their findings and submit them to the Conference of Radiation Control Program Directors.

Discussion (entire group)

DR. MILLER: This is a problem that we looked at, too, and we feel that the source-oriented stations that are going to continue to exist and should exist, like programs around the reactors or processing plants, should provide the extensive coverage needed to be able to adequately assess whatever the situation is. Obviously, in times of stress or emergency there is no question they are going to have to be added, but I think this will not pose a problem.

MR. SNOW: I don't recall the exact recommendation or the number, but there seem to be some inconsistencies that I would ask the committee to check on, perhaps by tomorrow. Namely, and I speak now with reference to one of the recommendations which applies to the Pasteurized Milk Network, that it should be discontinued. At the same time, there was another recommendation presented which encouraged the Bureau of Radiological Health to carry out its assessment of the national population exposure. Again, we rely both on the Pasteurized Milk Network to help us accomplish this so that, if the surveillance by the State is fully source oriented, I wonder whether or not we can extrapolate from these data into some national assessment on exposure.

MR. WILMS: Yes, we think that the source-oriented approach can provide the national picture, because in every source-oriented program there is one reference sampling point which is out of the sphere of influence of that source. These reference points should be able to take up the point of the national picture, because they should be unbiased. We would hope that there is not a conflict in our recommendations. I will discuss this with our committee, and if you think it should be looked into further, we will be glad to.

MR. VAN FAROWE: I wonder if the committee gave consideration to monitoring the source of radiation and perhaps the need for monitoring the reactor stacks directly.

MR. WILMS: No, we did not talk about the techniques of specific source sampling, whether we should have a continuous out-fall monitoring or stack monitoring, or this kind of thing. We didn't have time.

MR. VAN FAROWE: My second question is with regard to the need for uniformity among State monitoring systems. Environmental sampling for reactors differs from one State to another, and I wonder how this information would be tied together?

MR. WILMS: That is why we recommended some study here, because that is a big problem, of just how to achieve this. We could't tell in the short amount of time and limited knowledge and, of course, limited resources, as to how this problem could be solved. Before we can have meaningful data in this area, it seems to us that we should get them as comparable as possible and practical. It will help to assure us receiving comparable data. Now, there may be other ways to achieve this, but I don't know of any. This is one of the reasons we wanted to have this thing evaluated periodically, and work with these individual States through a center, like the Bureau of Radiological Health, to arrive at an acceptable solution.

MR. VAN FAROWE: Did you discuss at all the various surveillance programs performed by agencies other than the Federal Government?

MR. WILMS: They were brought in to the discussion. To do this, we tried to list them all. Many of these systems exist for reasons other than public health or are already source-oriented. The Public Health Service has a number of programs they do as contractors for outside agencies. We did feel it was probably beyond the scope of our group to make recommendations to agencies other than the Environmental Control Administration and the States here. We recognize they exist, they are there for political purposes in some cases, or they are source-related, and probably then our comments would not have any effect on them. One good example, perhaps, would be the Department of Defense High Altitude Surveillance Program, designed to detect the abrogation of the nuclear test ban.

Workshop No. 10

REVIEW OF DRAFT REGULATIONS FOR IMPLEMENTATION AND ADMINISTRATION OF PUBLIC LAW 90-602[1]

Marshall S. Little[2]

Our task was to review draft regulations for implementation and administration of Public Law 90-602. Some of you may not be aware that such draft regulations exist. Copies of these regulations are here on the table. These were not made available even to the workshop members until the first day of the conference, and, therefore, we did not have time to go over the detailed recommendations that might be needed for these regulations--at least in all areas. We covered, of course, portions of the proposed regulations as far as we could go, and we also gave consideration to general recommendations.

In brief, we might give a statement of our problem as follows:

a. Are the draft regulations adequate and sufficient to implement and administer the new law? If inadequacies exist, recommend amendments and justify.

b. To what extent and under what mechanism should appropriate State agencies participate in the development of regulations to implement Public Law 90-602?

Now, general recommendations are as follows:

a. Responsible State and local agencies should be given the opportunity to participate in the development of Federal radiation regulations at an early stage. As a mechanism for this participation, the workshop recommends that the initial drafts by the United States Public Health Service be distributed to the appropriate State and local agencies through the regional representatives of the Bureau of Radiological Health.

b. It is further suggested that States in a given region should collaborate in preparing comments. The proposal of one of the other workshops to form a committee under the Conference of Radiation Control Program Directors to review regulations was considered by our workshop and no position was taken on this proposal.

c. Some workshop members suggested that the Public Health Service should consider publishing in the Federal Register a declaration of intent, stating the procedures to be followed in implementing the act, together with a list of anticipated areas to be covered by regulations.

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[1] See Appendix A for membership of the workshop.

[2] Chief, Division of Radiological Health, District of Columbia Department of Public Health.

The background for this recommendation was the feeling by the workshop group that the act is extremely broad, and the proposed scope as indicated in these developed drafts is not clear. We feel, also, that in fairness to industry, some guidance should be given in advance of the regulations, to let industry know what types of devices are going to be subjected to regulations in the near future, and what will be the administrative procedure for enforcement of these regulations, and for implementing other aspects of the act.

d. In reviewing the proposed regulations, it appears that manufacturers, consumers, and official agencies may not be aware of the scope of electronic products to be regulated. Additional attention might be directed to better defining the electronic products to be regulated under the act. This is closely related to c, above.

e. It is recommended that the definitions be presented in the regulations only when the terms are not in accordance with generally accepted nomenclature. The workshop noted that most of the definitions in these proposed regulations were either inadequate or were not necessary.

Discussion (entire group)

MR. NEILL: I think Marshall did a good job in summarizing the points that were made, including Mr. Anderson's comments. If anybody has any additional comments, we would certainly appreciate it this evening, prior to the final presentation tomorrow.

Number one is on the definition of the term "defect." I mentioned this yesterday in my presentation here, and as Marshall has pointed out, we feel that it is both fair and essential to give manufacturers a clear definition of this.

Number two relates to the scope of electronic products to be regulated under the act. It is extremely difficult to define those products which will be regulated so that it is clear to industry as to what their responsibilities are, including records they will have to maintain. If there is any additional input you have in these areas, we would very much appreciate that, too.

DR. MILLER: Is there any comment from our official agency representative concerning the possibility of this notification of intent?

MR. FLORA: On that particular point of the recommendation, I would like to mention that certain procedures and formats published in the Federal Register are covered rather rigidly by our Federal Code, so that total flexibility is not possible in this area.

MR. LITTLE: I disagree with this, and I feel that my workshop will agree with me in saying that the act is extremely broad, and there are some very ill-defined areas that were left up to the Department of Health, Education, and Welfare, to define. We felt that these areas would more appropriately be defined prior to the regulations, and could be defined in a statement of intent published in the Federal Register.

I might give you an example. As you know, the act applies to two types of products; one which fails to comply with performance standards as they are drawn up by the Bureau and published in the Federal Register and Federal regulations, and number two, those which have a defect. Defect is not defined in the act.

The panel proposed this as a definition of defect:

> "An electronic product shall be considered to have a defect if, when used in normal or prescribed manner, it produces or may produce significant risk of somatic or genetic injury. Factors used in determining the significance of injury would be:
>
> a. Current standards of the Federal Radiation Council and the National Council on Radiation Protection and Measurements, International Council on Radiation Protection and Measurements, and the International Atomic Energy Agency,
>
> b. Current scientific knowledge of possible effects of such radiation, and
>
> c. Accepted good industrial practice."

SUMMARY SESSION

Thomas M. Gerusky

Last night the Workshop Chairmen and Cochairmen met to decide what were the significant recommendations from each of their workshops, and what they thought were general recommendations of the total conference The following are what we believe to be the general recommendations. I think these are really the meat of all the workshop reports, but they should not be taken out of context. I feel the recommendations of every workshop should stand on their own. This is just a general review of what went on, and I would like to discuss each one of them individually.

GENERAL RECOMMENDATIONS

1. That the Department of Health, Education, and Welfare should continue to expand its support of radiation control activities on the national, State, and local level.

2. That the first priority of a radiation control program will continue to be the reduction of unnecessary healing arts X-ray exposure.

3. That all radioactive materials, whether Atomic Energy Commission agreement materials or not, be regulated in the same nammer by the State and Federal radiation control agencies.

4. That the Department of Health, Education, and Welfare take appropriate steps to assume responsibility for regulating all sources of radiation in Federal installations presently not subject to complete regulation by the Atomic Energy Commission.

5. That radiation control programs expand their scope so as to encompass all various forms of radiation specified in Public Law 90-602, other than mechanical vibrations, as adopted by the Health Physics Society at its midwinter meeting in Los Angeles in January 1969.

6. That an ad hoc committee of State Radiation Control Program Directors be established to advise the Environmental Control Administration in the effective implementation of Public Law 90-602. A little comment on this one. It has been requested by Mr. Hansen and has been implemented already. The Executive Board of the Conference is making up the main body of the committee, and we will be in touch with Mr. Hansen's office next week.

7. That Federal, State, and local agencies participate together in the formulation of regulations, standards, and model State laws and regulations, and that State and local agencies utilize such models to assure uniformity and continuing compatibility among the various radiation control programs.

8. That the Department of Health, Education, and Welfare, the Atomic Energy Commission, and other interested Federal agencies, give continued support to the work of the Conference of Radiation Control Program Directors in this annual workshop.

9. That the Environmental Control Administration and the Atomic Energy Commission expand their support of training activities in radiation control, including short-term and university-based educational activities

10. That a request be made by the Conference of Radiation Control Program Directors for the National Council on Radiation Protection and Measurements to consider the problem of exposure to sources of non-ionizing radiation.

11. That environmental surveillance activities of the Federal Government be curtailed in favor of source-oriented flexible State environmental monitoring programs, with all such data collected made available for general distribution.

12. That continuing committees be established with representation from Federal, State, and local radiation control agencies, to further study and implement the specific recommendations of the various workshop committees.

CLOSING REMARKS

MR. GERUSKY: Gentlemen, I am real proud of you. I think you have done a tremendous job, and I think it is just the beginning. I don't want it to stop here. I know I have a lot of work to do back in Harrisburg, and I am sure you have much work to do in your own program. But I think the benefits of this meeting, just being here together and being able to talk, to discuss our problems and get some of the problems out in the open where they are easily and readily discussed, are just too important to walk away from and forget. For my part and the part of the Executive Board, and I am sure for most of the members of the conference, it is just the beginning. Thank you.

DR. McMARTIN: I am pleased to be able to be a part of something we have been thinking about for some three or four years now, and it has been a hard time getting on the road. We have made several starts. I know that Mr. Gerusky and some of the rest of the staff have gotten together several times, and there was always someone pulling the rug right out from under us. This is probably the first time that in one meeting, under one office, or under joint offices if you want to call it that, that we have gotten together all but two of the State and territorial directors of radiation control to sit down and talk with each other. This is important, because you really don't know each other until you have been working together for a while.

I want to commend all of you for the effort you have put in, and the diligence with which you have stuck to it. The fact that practically all of you are here at this last meeting is significant. I know that Mr. Hansen was more than pleased with your attitude, and with the fact that you wanted to be a part of this whole effort, insofar as Public Law 90-602 is concerned.

When Mr. Hansen told you that he was going to make a concerted effort to provide the States with support, whether financial, moral, personnel, or with information, I am certain he meant it. And, don't you ever get the idea that he didn't mean it when he said, "I'll expect a reciprocal response from you," because he did.

I would like at this time likewise to thank Mr. Morgan and Mr. Mason for participating in this program. We consider them sort of partners in the effort too, and I feel that perhaps it gave them an opportunity to talk to you in an atmosphere that hasn't been available to them before. From the standpoint of this group, thank you very much, and we will see to it that your bosses know of all the constructive things that you've done.

Mr. Hansen stated that when you have the authority you have to accept a certain amount of responsibility, and in this partnership business, if you want a part of the cake you have to help in the baking of it. This is not a one-way street, both of us have to come a little way. Now in this meeting I think we have come a long way toward meeting a joint responsibility and a joint response in the implementation of this law. Let us not forget that this law is not complete. This is just the beginning. Section 357 calls for additional studies, calls for reports that will make recommendations for new laws, new legislation, an amendment to the present law. It is a dynamic action, rather than something that is static.

The regional relationships, as far as Mr. Hansen is concerned, are going to have to be strengthened. I think that from Mr. Johnson[1] on down there is a sincere desire to get our efforts in environmental health down to a level as close to the people as possible. If they don't succeed in doing this, they both feel that they won't be criticized for not trying.

This is going to be your opportunity to be a partner in the implementation of Public Law 90-602. As much as can be done will be done to give you the support and help you need in strengthening your programs, and to improve to the point of acceptance those programs which at the present time have less than minimal programming activities available to them.

I am not going to go over any of the deliberations or review any of the papers, or any of the recommendations, because you have had enough of this. I would like to say that when you have been given an opportunity to speak out in behalf of the group, I believe you will be listened to and heard. We've a job to do. It is a mutual problem that we have to solve and I think that we don't have to be disagreeable just because we disagree once in awhile. But most important of all--"let's get at it."

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[1] Commissioner, Consumer Protection and Environmental Health Service, Public Health Service.

DR. MILLER: Thank you, Dr. McMartin, for that excellent summation. We have discussed at this meeting a lot of things which could make us do our job more efficiently in controlling radiation nationally. What becomes of all the effort we have put in this week depends on what is done in the future, between the relationships that we have established and the hard work we have put in this week. This has to continue.

APPENDIXES

APPENDIX A

WORKSHOP MEMBERSHIP

APPENDIX A

Workshop No. 1

COMPATIBILITY

Roy A. Parker, Ph.D., Louisiana, Chairman
James A. McTaggart, D.D.S., PHS Dallas Regional Office, Cochairman

Harry Gilbert	District of Columbia
Jerry L. Yoder	Idaho
Robert C. Will	Kansas
G. R. Farmer, M.D.	Oregon
William L. Lea, M.D.	Wisconsin
David H. Flora	BRH, Public Health Service
Lloyd R. Setter, Ph.D.	BRH, Public Health Service
John C. Villforth	BRH, Public Health Service
James R. Mason	Atomic Energy Commission

Workshop No. 2

STATE-FEDERAL ROLE IN RADIATION CONTROL

Simon Kinsman, Ph.D., California, Chairman
Clifford E. Nelson, M.D., PHS San Francisco Regional Office, Cochairman

David D. Snellings	Arkansas
E. G. Williams, M.D.	Florida
Forrest H. Bumford	New Hampshire
Harry Farkas	New York
Gene Christianson	North Dakota
M. W. Carter, Ph.D.	SWRHL,Public Health Service
H. L. McMartin	ECA, Public Health Service
R. L. Elder, Sc.D.	BRH, Public Health Service
W. A. Mills, Ph.D.	BRH, Public Health Service
D. J. Nelson, Jr.	BRH, Public Health Service
B. Bruckner, Ph.D.	BRH, Public Health Service
William Morgan	Atomic Energy Commission

Workshop No. 3

CRITERIA AND/OR INDICES, PROGRAM EVALUATION AND MEASURES OF PROGRESS

William T. Willis, Alabama, Chairman
Richard H. Payne, PHS Atlanta Regional Office, Cochairman

William L. Wagner	PHS Assignee, Alaska
B. Jim Porter	Louisiana
Donald C. Hoxie	Maine
Donald G. Kurvink	South Dakota
Harvey J. Roberts	West Virginia
D. L. Snow	BRH, Public Health Service
James M. Conlon	BRH, Public Health Service
Robert G. Britain	BRH, Public Health Service
Paul L. Roney	BRH, Public Health Service

Workshop No. 4

REVIEW OF CURRENT STANDARDS FOR ELECTRONIC PRODUCTS

Robert D. Siek, Colorado, Chairman
Paul B. Smith, PHS Denver Regional Office, Cochairman

Donald C. Gilbert	Arizona
Henry Karp	Georgia
Leroy E. Stratton	Illinois
F. J. Bradley, Ph.D.	New York
James A. Kraeger	PHS Assignee, North Dakota
Bryce P. Schofield	Virginia
D. L. Solem	BRH, Public Health Service
R. F. Boggs	BRH, Public Health Service
Alan A. Moghissi, Ph.D.	SERHL, Public Health Service
Charles R. Phillips	SERHL, Public Health Service

NOTE:

Report presented by Dr. Bradley for Mr. Siek.

Workshop No. 5

REVIEW OF CURRENT STANDARDS FOR CONTROL OF NON-ATOMIC ENERGY COMMISSION MATERIAL

Henry C. Briggs, Indiana, Chairman
Jerome A. Halperin, PHS Chicago Regional Office, Cochairman

E. Lee Stein	Delaware
Richard H. Fetz	Georgia
Martin C. Wukasch	Texas
Ray McCandless	Vermont
Beattie DeBord	West Virginia
Allan C. Tapert	PHS Assignee, Wisconsin
E. W. Robinson	BRH, Public Health Service
Paul H. Bedrosian, Ph.D.	SERHL, Public Health Service

Workshop No. 6

CONTROL OF ELECTRONIC PRODUCTS AT THE STATE LEVEL

Gerald S. Parker, Massachusetts, Chairman
Byron E. Keene, PHS Boston Regional Office, Cochairman

Aubrey Godwin	Alabama
Charles L. Campbell, Ph.D.	Iowa
Wendell McCurry	Nevada
William G. Crosby	South Carolina
J. A. Bill Graham	Tennessee
John E. Regnier, Ph.D.	SERHL, Public Health Service
L. C. Seabron	BRH, Public Health Service

Workshop No. 7

PERFORMANCE STANDARDS FOR RADIATION USERS

William H. Aaroe, New Jersey, Chairman
Robert Frankel, PHS New York Regional Office, Cochairman

E. F. Wilson	Arkansas
E. A. Fullgrabe, M.D.	Missouri
Dayne H. Brown	North Carolina
Amalia Velez	Puerto Rico
Arnold J. Moen	Washington
Joseph Brennan	NERHL, Public Health Service
W. S. Cole, M.D.	BRH, Public Health Service

Workshop No. 8

INSPECTIONS AND RECORDS, UNIFORMITY AND UTILIZATION

Richard M. Fry, Kentucky, Chairman
Norman A. Geiger, PHS Charlottesville Regional Office, Cochairman

Bobby L. Dillard	PHS Assignee, Kentucky
Donald E. Van Farowe	Michigan
Eddie S. Fuente	Mississippi
Richard A. Lane	Montana
Samuel Ingraham, II, M.D.	New Jersey
John W. Shaver	North Carolina
Jesse Lieberman	Pennsylvania
J. E. Cowan	BRH, Public Health Service
M. Rosenstein	BRH, Public Health Service

Workshop No. 9

STATE VERSUS FEDERAL SURVEILLANCE NETWORKS

Heinz G. Wilms, Nebraska, Chairman
G. A. Jacobson, PHS Kansas City Regional Office, Cochairman

Cecil D. Posey	Georgia
Robert E. Corcoran	Maryland
Aaron Bond	New Mexico
James P. Deery, M.D.	Rhode Island
Dennis Dalley	Utah
Gerald J. Karches	NERHL, Public Health Service
Charles R. Porter	SERHL, Public Health Service
C. L. Weaver	BRH, Public Health Service
Bernd Kahn, Ph.D.	BRH, Public Health Service

Workshop No. 10

REVIEW OF DRAFT REGULATIONS FOR IMPLEMENTATION AND ADMINISTRATION OF PUBLIC LAW 90-602

Marshall S. Little, District of Columbia, Chairman
Saul J. Harris, PHS New York Regional Office, Cochairman

George J. Raschka	Minnesota
Daniel Lynch	New York
James Wynd	Ohio
J. Dale McHard	Oklahoma
Robert E. Sundin	Wyoming
R. H. Neill	BRH, Public Health Service
Don R. Roberts	Tennessee

APPENDIX B

Public Law 90-602
90th Congress, H. R. 10790
October 18, 1968

An Act

To amend the Public Health Service Act to provide for the protection of the public health from radiation emissions from electronic products.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Radiation Control for Health and Safety Act of 1968.

SHORT TITLE

SECTION 1. This Act may be cited as the "Radiation Control for Health and Safety Act of 1968".

AMENDMENTS TO PUBLIC HEALTH SERVICE ACT

SEC. 2. Part F of title III of the Public Health Service Act is amended—

58 Stat. 703; 81 Stat. 536. 42 USC 262-263a.

(1) by striking out the heading for such part and inserting in lieu thereof the following:

"PART F—LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES AND CONTROL OF RADIATION

"SUBPART 1—BIOLOGICAL PRODUCTS";

(2) by inserting immediately above the section heading of section 353 the following:

"SUBPART 2—CLINICAL LABORATORIES"; and

(3) by adding at the end of such part F the following new subpart:

"SUBPART 3—ELECTRONIC PRODUCT RADIATION CONTROL

"DECLARATION OF PURPOSE

"SEC. 354. The Congress hereby declares that the public health and safety must be protected from the dangers of electronic product radiation. Thus, it is the purpose of this subpart to provide for the establishment by the Secretary of an electronic product radiation control program which shall include the development and administration of performance standards to control the emission of electronic product radiation from electronic products and the undertaking by public and private organizations of research and investigation into the effects and control of such radiation emissions.

82 STAT. 1173
82 STAT. 1174

"DEFINITIONS

"SEC. 355. As used in this subpart—

"(1) the term 'electronic product radiation' means—

"(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or

"(B) any sonic, infrasonic, or ultrasonic wave,

which is emitted from an electronic product as the result of the operation of an electronic circuit in such product;

"(2) the term 'electronic product' means (A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) elec-

tronic product radiation, or (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation:

"(3) the term 'manufacturer' means any person engaged in the business of manufacturing, assembling, or importing of electronic products;

"(4) the term 'commerce' means (A) commerce between any place in any State and any place outside thereof; and (B) commerce wholly within the District of Columbia; and

"(5) the term 'State' includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

"ELECTRONIC PRODUCT RADIATION CONTROL PROGRAM

"SEC. 356. (a) The Secretary shall establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation. As a part of such program, he shall—

"(1) pursuant to section 358, develop and administer performance standards for electronic products;

"(2) plan, conduct, coordinate, and support research, development, training, and operational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation;

82 STAT. 1174
82 STAT. 1175

"(3) maintain liaison with and receive information from other Federal and State departments and agencies with related interests, professional organizations, industry, industry and labor associations, and other organizations on present and future potential electronic product radiation;

"(4) study and evaluate emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields;

"(5) develop, test, and evaluate the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation; and

"(6) consult and maintain liaison with the Secretary of Commerce, the Secretary of Defense, the Secretary of Labor, the Atomic Energy Commission, and other appropriate Federal departments and agencies on (A) techniques, equipment, and programs for testing and evaluating electronic product radiation, and (B) the development of performance standards pursuant to section 358 to control such radiation emissions.

"(b) In carrying out the purposes of subsection (a), the Secretary is authorized to—

"(1)(A) collect and make available, through publications and other appropriate means, the results of, and other information concerning, research and studies relating to the nature and extent of the hazards and control of electronic product radiation: and (B) make such recommendations relating to such hazards and control as he considers appropriate;

"(2) make grants to public and private agencies, organizations, and institutions, and to individuals for the purposes stated in paragraphs (2), (4), and (5) of subsection (a) of this section;

"(3) contract with public or private agencies, institutions, and organizations, and with individuals, without regard to sections 3648 and 3709 of the Revised Statutes of the United States (31 U.S.C. 529, 41 U.S.C. 5); and

"(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products.

"(c)(1) Each recipient of assistance under this subpart pursuant to grants or contracts entered into under other than competitive bidding procedures shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such assistance, the total cost of the project or undertaking in connection with which such assistance is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

"(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients that are pertinent to the grants or contracts entered into under this subpart under other than competitive bidding procedures.

82 STAT. 1175
82 STAT. 1176

"STUDIES BY THE SECRETARY

"SEC. 357. (a) The Secretary shall conduct the following studies, and shall make a report or reports of the results of such studies to the Congress on or before January 1, 1970, and from time to time thereafter as he may find necessary, together with such recommendations for legislation as he may deem appropriate:

Report to Congress.

"(1) A study of present State and Federal control of health hazards from electronic product radiation and other types of ionizing radiation, which study shall include, but not be limited to—

"(A) control of health hazards from radioactive materials other than materials regulated under the Atomic Energy Act of 1954;

68 Stat. 919.
42 USC 2011 note.

"(B) any gaps and inconsistencies in present controls;

"(C) the need for controlling the sale of certain used electronic products, particularly antiquated X-ray equipment, without upgrading such products to meet the standards for new products or separate standards for used products;

"(D) measures to assure consistent and effective control of the aforementioned health hazards;

"(E) measures to strengthen radiological health programs of State governments; and

"(F) the feasibility of authorizing the Secretary to enter into arrangements with individual States or groups of States to define their respective functions and responsibilities for the control of electronic product radiation and other ionizing radiation;

"(2) A study to determine the necessity for the development of standards for the use of nonmedical electronic products for commercial and industrial purposes; and

"(3) A study of the development of practicable procedures for the detection and measurement of electronic product radiation which may be emitted from electronic products manufactured or imported prior to the effective date of any applicable standard established pursuant to this subpart.

"(b) In carrying out these studies, the Secretary shall invite the participation of other Federal departments and agencies having related responsibilities and interests, State governments—particularly those of States which regulate radioactive materials under section 274 of the Atomic Energy Act of 1954, as amended, and interested professional, labor, and industrial organizations. Upon request from congressional committees interested in these studies, the Secretary shall keep these committees currently informed as to the progress of the

73 Stat. 688.
42 USC 2021.

studies and shall permit the committees to send observers to meetings of the study groups.

"(c) The Secretary or his designee shall organize the studies and the participation of the invited participants as he deems best. Any dissent from the findings and recommendations of the Secretary shall be included in the report if so requested by the dissenter.

82 STAT. 1176

82 STAT. 1177

"PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS

"SEC. 358. (a)(1) The Secretary shall by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from such products if he determines that such standards are necessary for the protection of the public health and safety. Such standards may include provisions for the testing of such products and the measurement of their electronic product radiation emissions, may require the attachment of warning signs and labels, and may require the provision of instructions for the installation, operation, and use of such products. Such standards may be prescribed from time to time whenever such determinations are made, but the first of such standards shall be prescribed prior to January 1, 1970. In the development of such standards, the Secretary shall consult with Federal and State departments and agencies having related responsibilities or interests and with appropriate professional organizations and interested persons, including representatives of industries and labor organizations which would be affected by such standards, and shall give consideration to—

"(A) the latest available scientific and medical data in the field of electronic product radiation;

"(B) the standards currently recommended by (i) other Federal agencies having responsibilities relating to the control and measurement of electronic product radiation, and (ii) public or private groups having an expertise in the field of electronic product radiation;

"(C) the reasonableness and technical feasibility of such standards as applied to a particular electronic product;

"(D) the adaptability of such standards to the need for uniformity and reliability of testing and measuring procedures and equipment; and

"(E) in the case of a component, or accessory described in paragraph (2)(B) of section 355, the performance of such article in the manufactured or assembled product for which it is designed.

"(2) The Secretary may prescribe different and individual performance standards, to the extent appropriate and feasible, for different electronic products so as to recognize their different operating characteristics and uses.

"(3) The performance standards prescribed under this section shall not apply to any electronic product which is intended solely for export if (A) such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and (B) such product meets all the applicable requirements of the country to which such product is intended for export.

"(4) The Secretary may by regulation amend or revoke any performance standard prescribed under this section.

"(5) The Secretary may exempt from the provisions of this section any electronic product intended for use by departments or agencies of the United States provided such department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the United States.

"(b) The provisions of subchapter II of chapter 5 of title 5 of the United States Code (relating to the administrative procedure for rulemaking), and of chapter 7 of such title (relating to judicial review), shall apply with respect to any regulation prescribing, amending, or revoking any standard prescribed under this section.

80 Stat. 381.
5 USC 551.

Publication in Federal Register.

"(c) Each regulation prescribing, amending, or revoking a standard shall specify the date on which it shall take effect which, in the case of any regulation prescribing, or amending any standard, may not be sooner than one year or not later than two years after the date on which such regulation is issued, unless the Secretary finds, for good cause shown, that an earlier or later effective date is in the public interest and publishes in the Federal Register his reason for such finding, in which case such earlier or later date shall apply.

Petition for judicial review.

"(d)(1) In a case of actual controversy as to the validity of any regulation issued under this section prescribing, amending, or revoking a performance standard, any person who will be adversely affected by such regulation when it is effective may at any time prior to the sixtieth day after such regulation is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such regulation. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based the regulation, as provided in section 2112 of title 28 of the United States Code.

72 Stat. 941;
80 Stat. 1323.

"(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendations, if any, for the modification or setting aside of his original regulation, with the return of such additional evidence.

"(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to review the regulation in accordance with chapter 7 of title 5 of the United States Code and to grant appropriate relief as provided in such chapter.

"(4) The judgment of the court affirming or setting aside, in whole or in part, any such regulation of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code.

62 Stat. 928.

"(5) Any action instituted under this subsection shall survive, notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

"(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

"(e) A certified copy of the transcript of the record and administrative proceedings under this section shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, exclusion of imports, or other proceeding arising under or in respect of this subpart, irrespective of whether proceedings with respect to the regulation have previously been initiated or become final under this section.

Technical Electronic Product Radiation Safety Standards Committee.

"(f)(1)(A) The Secretary shall establish a Technical Electronic Product Radiation Safety Standards Committee (hereafter in this subpart referred to as the 'Committee') which he shall consult before prescribing any standard under this section. The Committee shall be appointed by the Secretary, after consultation with public and private agencies concerned with the technical aspect of electronic product radiation safety, and shall be composed of fifteen members each of whom shall be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety, as follows:

"(i) Five members shall be selected from governmental agencies, including State and Federal Governments;

"(ii) Five members shall be selected from the affected industries after consultation with industry representatives; and

"(iii) Five members shall be selected from the general public, of which at least one shall be a representative of organized labor.

Safety standards, proposal.

"(B) The Committee may propose electronic product radiation safety standards to the Secretary for his consideration. All proceedings of the Committee shall be recorded and the record of each such proceeding shall be available for public inspection.

Compensation.

"(2) Members of the Committee who are not officers or employees of the United States shall, while attending meetings or conferences of the Committee or otherwise engaged in the business of the Committee, be entitled to receive compensation at a rate fixed by the Secretary, but not exceeding $100 per diem (including traveltime), and while away from their homes or regular places of business they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized in section 5703 of title 5 of the United States Code for persons in the Government service employed intermittently. Payments under this subsection shall not render members of the Committee officers or employees of the United States for any purpose.

80 Stat. 499.

Review and evaluation.

"(g) The Secretary shall review and evaluate on a continuing basis testing programs carried out by industry to assure the adequacy of safeguards against hazardous electronic product radiation and to assure that electronic products comply with standards prescribed under this section.

Product certification.

"(h) Every manufacturer of an electronic product to which is applicable a standard in effect under this section shall furnish to the distributor or dealer at the time of delivery of such product, in the form of a label or tag permanently affixed to such product or in such manner as approved by the Secretary, the certification that such product conforms to all applicable standards under this section. Such certification shall be based upon a test, in accordance with such standard, of the individual article to which it is attached or upon a testing program which is in accord with good manufacturing practice and which has not been disapproved by the Secretary (in such manner as he shall prescribe by regulation) on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standards prescribed under this section.

"NOTIFICATION OF DEFECTS IN, AND REPAIR OR REPLACEMENT OF, ELECTRONIC PRODUCTS

"SEC. 359. (a)(1) Every manufacturer of electronic products who discovers that an electronic product produced, assembled, or imported by him has a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation, or that an electronic product produced, assembled, or imported by him on or after the effective date of an applicable standard prescribed pursuant to section 358 fails to comply with such standard, shall immediately notify the Secretary of such defect or failure to comply if such product has left the place of manufacture and shall (except as authorized by paragraph (2)) with reasonable promptness furnish notification of such defect or failure to the persons (where known to the manufacturer) specified in subsection (b) of this section.

"(2) If, in the opinion of such manufacturer, the defect or failure to comply is not such as to create a significant risk of injury, including genetic injury, to any person, he may, at the time of giving notice to the Secretary of such defect or failure to comply, apply to the Secretary for an exemption from the requirement of notice to the persons specified in subsection (b). If such application states reasonable grounds for such exemption, the Secretary shall afford such manufacturer an opportunity to present his views and evidence in support of the application, the burden of proof being on the manufacturer. If, after such presentation, the Secretary is satisfied that such defect or failure to comply is not such as to create a significant risk of injury, including genetic injury, to any person, he shall exempt such manufacturer from the requirement of notice to the persons specified in subsection (b) of this section and from the requirements of repair or replacement imposed by subsection (f) of this section.

"(b) The notification (other than to the Secretary) required by paragraph (1) of subsection (a) of this section shall be accomplished—

"(1) by certified mail to the first purchaser of such product for purposes other than resale, and to any subsequent transferee of such product; and

"(2) by certified mail or other more expeditious means to the dealers or distributors of such manufacturer to whom such product was delivered.

"(c) The notifications required by paragraph (1) of subsection (a) of this section shall contain a clear description of such defect or failure to comply with an applicable standard, an evaluation of the hazard reasonably related to such defect or failure to comply, and a statement of the measures to be taken to repair such defect. In the case of a notification to a person referred to in subsection (b) of this section, the notification shall also advise the person of his rights under subsection (f) of this section.

"(d) Every manufacturer of electronic products shall furnish to the Secretary a true or representative copy of all notices, bulletins, and other communications to the dealers or distributors of such manufacturer or to purchasers (or subsequent transferees) of electronic products of such manufacturer regarding any such defect in such product or any such failure to comply with a standard applicable to such product. The Secretary shall disclose to the public so much of the information contained in such notice or other information obtained under section 360A as he deems will assist in carrying out the purposes of this subpart, but he shall not disclose any information which contains or relates to a trade secret or other matter referred to in section 1905 of title 18 of the United States Code unless he determines that it is necessary to carry out the purposes of this subpart. 62 Stat. 791.

"(e) If through testing, inspection, investigation, or research carried out pursuant to this subpart, or examination of reports submitted pursuant to section 360A, or otherwise, the Secretary determines that any electronic product—

"(1) does not comply with an applicable standard prescribed pursuant to section 358; or

"(2) contains a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation;

he shall immediately notify the manufacturer of such product of such defect or failure to comply. The notice shall contain the findings of the Secretary and shall include all information upon which the findings are based. The Secretary shall afford such manufacturer an opportunity to present his views and evidence in support thereof, to establish that there is no failure of compliance or that the alleged defect does not exist or does not relate to safety of use of the product by reason of the emission of such radiation hazard. If after such presentation by the manufacturer the Secretary determines that such product does not comply with an applicable standard prescribed pursuant to section 358, or that it contains a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation, the Secretary shall direct the manufacturer to furnish the notification specified in subsection (c) of this section to the persons specified in paragraphs (1) and (2) of subsection (b) of this section (where known to the manufacturer), unless the manufacturer has applied for an exemption from the requirement of such notification on the ground specified in paragraph (2) of subsection (a) and the Secretary is satisfied that such noncompliance or defect is not such as to create a significant risk of injury, including genetic injury, to any person.

"(f) If any electronic product is found under subsection (a) or (e) to fail to comply with an applicable standard prescribed under this subpart or to have a defect which relates to the safety of use of such product, and the notification specified in subsection (c) is required to be furnished on account of such failure or defect, the manufacturer of such product shall (1) without charge, bring such product into conformity with such standard or remedy such defect and provide reimbursement for any expenses for transportation of such product incurred in connection with having such product brought into conformity or having such defect remedied, (2) replace such product with a like or equivalent product which complies with each applicable standard prescribed under this subpart and which has no defect relating to the safety of its use, or (3) make a refund of the cost of such product. The manufacturer shall take the action required by this subsection in such manner, and with respect to such persons, as the Secretary by regulations shall prescribe.

"(g) This section shall not apply to any electronic product that was manufactured before the date of the enactment of this subpart.

"IMPORTS

"SEC. 360. (a) Any electronic product offered for importation into the United States which fails to comply with an applicable standard prescribed under this subpart, or to which is not affixed a certification in the form of a label or tag in conformity with section 358(h) shall be refused admission into the United States. The Secretary of the Treasury shall deliver to the Secretary of Health, Education, and Welfare, upon the latter's request, samples of electronic products which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may have a hearing before the Secretary of Health, Education, and Welfare. If it appears from an examination of such samples or otherwise that any electronic product fails to comply with applicable standards prescribed pursuant to section 358, then, unless subsection (b) of this section applies and is complied with, (1) such electronic product shall be refused admission, and (2) the Secretary of the Treasury shall cause the destruction of such electronic product unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days after the date of notice of refusal of admission or within such additional time as may be permitted by such regulations.

"(b) If it appears to the Secretary of Health, Education, and Welfare that any electronic product refused admission pursuant to subsection (a) of this section can be brought into compliance with applicable standards prescribed pursuant to section 358, final determination as to admission of such electronic product may be deferred upon filing of timely written application by the owner or consignee and the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as the Secretary of Health, Education, and Welfare may by regulation prescribe. If such application is filed and such bond is executed the Secretary of Health, Education, and Welfare may, in accordance with rules prescribed by him, permit the applicant to perform such operations with respect to such electronic product as may be specified in the notice of permission.

"(c) All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of operations provided for in subsection (b) of this section, and all expenses in connection with the storage, cartage, or labor with respect to any electronic product refused admission pursuant to subsection (a) of this section, shall be paid by the owner or consignee, and, in event of default, shall constitute a lien against any future importations made by such owner or consignee.

"(d) It shall be the duty of every manufacturer offering an electronic product for importation into the United States to designate in writing an agent upon whom service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made for and on behalf of said manufacturer, and to file such designation with the Secretary, which designation may from time to time be changed by like writing, similarly filed. Service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made upon said manufacturer by service upon such designated agent at his office or usual place of residence with like effect as if made personally upon said manufacturer, and in default of such designation of such agent, service of process, notice, order, requirement, or decision in any proceeding before the Secretary or in any judicial proceeding for enforcement of this subpart or any standards prescribed pursuant to this subpart may be made by posting such process, notice, order, requirement, or decision in the Office of the Secretary or in a place designated by him by regulation.

"Sec. 360A. (a) If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times, any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 358(h) are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this subpart and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 359(a)(2) or 359(e).

"(b) Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this subpart and standards prescribed pursuant to this subpart and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to this subpart.

"(c) Every manufacturer of electronic products shall provide to the Secretary such performance data and other technical data related to safety as may be required to carry out the purposes of this subpart. The Secretary is authorized to require the manufacturer to give such notification of such performance and technical data at the time of original purchase to the ultimate purchaser of the electronic product, as he determines necessary to carry out the purposes of this subpart after consulting with the affected industry.

"(d) Accident and investigation reports made under this subpart by any officer, employee, or agent of the Secretary shall be available for use in any civil, criminal, or other judicial proceeding arising out of such accident. Any such officer, employee, or agent may be required to testify in such proceedings as to the facts developed in such investigations. Any such report shall be made available to the public in a manner which need not identify individuals. All reports on research projects, demonstration projects, and other related activities shall be public information.

"(e) The Secretary or his representative shall not disclose any information reported to or otherwise obtained by him, pursuant to subsection (a) or (b) of this section, which concerns any information which contains or relates to a trade secret or other matter referred to in section 1905 of title 18 of the United States Code, except that such information may be disclosed to other officers or employees of the Department and of other agencies concerned with carrying out this subpart or when relevant in any proceeding under this subpart. Nothing in this section shall authorize the withholding of information by the Secretary, or by any officers or employees under his control, from the duly authorized committees of the Congress.

62 Stat. 791.

"(f) The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this subpart and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 359, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information.

Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer, to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 359, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefor for the purposes of section 359, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 359(a).

"PROHIBITED ACTS

"SEC. 360B. (a) It shall be unlawful—

"(1) for any manufacturer to introduce, or to deliver for introduction, into commerce, or to import into the United States, any electronic product which does not comply with an applicable standard prescribed pursuant to section 358;

"(2) for any person to fail to furnish any notification or other material or information required by section 359 or 360A; or to fail to comply with the requirements of section 359(f);

"(3) for any person to fail or to refuse to establish or maintain records required by this subpart or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required by or pursuant to section 360A;

"(4) for any person to fail or to refuse to make any report required pursuant to section 360A(b) or to furnish or preserve any information required pursuant to section 360A(f); or

"(5) for any person (A) to fail to issue a certification as required by section 358(h), or (B) to issue such a certification when such certification is not based upon a test or testing program meeting the requirements of section 358(h) or when the issuer, in the exercise of due care, would have reason to know that such certification is false or misleading in a material respect.

"(b) The Secretary may exempt any electronic product, or class thereof, from all or part of subsection (a), upon such conditions as he may find necessary to protect the public health or welfare, for the purpose of research, investigations, studies, demonstrations, or training, or for reasons of national security.

"ENFORCEMENT

"SEC. 360C. (a) The district courts of the United States shall have jurisdiction, for cause shown, to restrain violations of section 360B and to restrain dealers and distributors of electronic products from selling or otherwise disposing of electronic products which do not conform to an applicable standard prescribed pursuant to section 358 except when such products are disposed of by returning them to the distributor or manufacturer from whom they were obtained. The district courts of the United States shall also have jurisdiction in accordance with section 1355 of title 28 of the United States Code to enforce the provisions of subsection (b) of this section.

62 Stat. 934.

"(b)(1) Any person who violates section 360B shall be subject to a civil penalty of not more than $1,000. For purposes of this subsection, any such violation shall with respect to each electronic product involved, or with respect to each act or omission made unlawful by section 360B, constitute a separate violation, except that the maximum civil penalty imposed on any person under this subsection for any related series of violations shall not exceed $300,000.

"(2) Any such civil penalty may on application be remitted or mitigated by the Secretary. In determining the amount of such penalty, or whether it should be remitted or mitigated and in what amount, the appropriateness of such penalty to the size of the business of the person charged and the gravity of the violation shall be considered. The amount of such penalty, when finally determined, may be deducted from any sums owing by the United States to the person charged.

"(c) Actions under subsections (a) and (b) of this section may be brought in the district court of the United States for the district wherein any act or omission or transaction constituting the violation occurred, or in such court for the district where the defendant is found or transacts business, and process in such cases may be served in any other district of which the defendant is an inhabitant or wherever the defendant may be found.

"(d) Nothing in this subpart shall be construed as requiring the Secretary to report for the institution of proceedings minor violations of this subpart whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

"(e) Except as provided in the first sentence of section 360F, compliance with this subpart or any regulations issued thereunder shall not relieve any person from liability at common law or under statutory law.

"(f) The remedies provided for in this subpart shall be in addition to and not in substitution for any other remedies provided by law.

"ANNUAL REPORT

Report to Congress.

"SEC. 360D. (a) The Secretary shall prepare and submit to the President for transmittal to the Congress on or before April 1 of each year a comprehensive report on the administration of this subpart for the preceding calendar year. Such report shall include—

"(1) a thorough appraisal (including statistical analyses, estimates, and long-term projections) of the incidence of biological injury and effects, including genetic effects, to the population resulting from exposure to electronic product radiation, with a breakdown, insofar as practicable, among the various sources of such radiation;

"(2) a list of Federal electronic product radiation control standards prescribed or in effect in such year, with identification of standards newly prescribed during such year;

"(3) an evaluation of the degree of observance of applicable standards, including a list of enforcement actions, court decisions, and compromises of alleged violations by location and company name;

"(4) a summary of outstanding problems confronting the administration of this subpart in order of priority;

"(5) an analysis and evaluation of research activities completed as a result of Government and private sponsorship, and technological progress for safety achieved during such year;

"(6) a list, with a brief statement of the issues, of completed or pending judicial actions under this subpart;

"(7) the extent to which technical information was disseminated to the scientific, commercial, and labor community and consumer-oriented information was made available to the public; and

"(8) the extent of cooperation between Government officials and representatives of industry and other interested parties in the implementation of this subpart including a log or summary of meetings held between Government officials and representatives of industry and other interested parties.

"(b) The report required by subsection (a) shall contain such recommendations for additional legislation as the Secretary deems necessary to promote cooperation among the several States in the improvement of electronic product radiation control and to strengthen the national electronic product radiation control program.

"FEDERAL-STATE COOPERATION

"SEC. 360E. The Secretary is authorized (1) to accept from State and local authorities engaged in activities related to health or safety or consumer protection, on a reimbursable basis or otherwise, any assistance in the administration and enforcement of this subpart which he may request and which they may be able and willing to provide and, if so agreed, may pay in advance or otherwise for the reasonable cost of such assistance, and (2) he may, for the purpose of conducting examinations, investigations, and inspections, commission any officer or employee of any such authority as an officer of the Department.

"EFFECT ON STATE STANDARDS

"SEC. 360F. Whenever any standard prescribed pursuant to section 358 with respect to an aspect of performance of an electronic product is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, any standard which is applicable to the same aspect of performance of such product and which is not identical to the Federal standard. Nothing in this subpart shall be construed to prevent the Federal Government or the government of any State or political subdivision thereof from establishing a requirement with respect to emission of radiation from electronic products procured for its own use if such requirement imposes a more restrictive standard than that required to comply with the otherwise applicable Federal standard."

DEFINITIONS

SEC. 3. As used in the amendments made by section 2 of this Act, except when otherwise specified, the term "Secretary" means the Secretary of Health, Education, and Welfare, and the term "Department" means the Department of Health, Education, and Welfare.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

SEC. 4. The amendments made by section 2 of this Act shall not be construed as superseding or limiting the functions, under any other provision of law, of any officer or agency of the United States.

Approved October 18, 1968.

LEGISLATIVE HISTORY:

HOUSE REPORTS: No. 1166 (Comm. on Interstate and Foreign Commerce) and No. 1971 (Comm. of Conference).
SENATE REPORT No. 1432 (Comm. on Commerce).
CONGRESSIONAL RECORD, Vol. 114 (1968):
Mar. 20: Considered and passed House.
Oct. 2, 3: Considered and passed Senate, amended.
Oct. 11: House and Senate agreed to conference report.